IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 23
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 9, 2021

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Proceedings recorded by mechanical stenography;
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PROCEEDINGS had before The Honorable David A. Faber, Senior Status Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on June 9, 2021, at 9:00 a.m., as follows:

THE COURT: Mr. Fuller, you have something you want to bring up?

MR. FULLER: Judge, just real briefly. We had previously admitted P-14288 that didn't have page numbers on it and it is a voluminous document, so we're going to substitute in, with the Court's permission, a paginated version.

And then P-14290, these are Cardinal's policies and procedures. Cardinal has no objection and the clerk said it was okay to give it to her on a thumb drive because it's voluminous, if that's all right with the Court.

THE COURT: Okay. You may do so, Mr. Fuller.

MR. FULLER: Thank you, Judge.

THE COURT: I have what I think will be welcome news. In consultation with the Chief Judge and the Clerk of Court, I'm authorized to tell you that fully vaccinated individuals can go without masks while in the courtroom.

(Applause)

THE COURT: In this courtroom. And you still have to comply with the mask order while in common areas and

maintain the occupational limits that were put in place at the beginning of the trial and these rules are being constantly re-evaluated, I'm told, but at least while you're in this courtroom, you don't have to wear the masks.

SIMULTANEOUS SPEAKERS: Thank you, Your Honor.

THE COURT: So, I'm no longer setting a bad example.

(Laughter)

THE COURT: Also, I'm struggling about the time limitations on the court and I am trying to work through a proposal for you on that, but for now, unless somebody has travel plans that are going to be totally disrupted by this, we will go until 5:00 on Friday. Is that a problem with anybody? I see no -- okay.

And I'm trying to figure out a way to maybe allow a little more time without disrupting the trial schedule, but I'll try to have a proposal to you for that shortly.

Are we ready to go with Mr. Rannazzisi?

Are you in the courtroom, sir?

MR. SCHMIDT: May I take the podium, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: Thank you.

THE COURT: And, Mr. Rannazzisi, you don't have to wear the mask anymore in this courtroom, but you have to follow all the other rules that are in place.

THE WITNESS: Thank you very much, Judge. That's great.

THE COURT: The abominable masks.

THE WITNESS: And good morning, Your Honor.

THE COURT: Good morning, sir.

You may proceed, Mr. Schmidt.

MR. SCHMIDT: Thank you, Your Honor.

Good morning, Mr. Rannazzisi.

THE WITNESS: Good morning.

MR. SCHMIDT: Good morning again, Your Honor.

May I approach?

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, I'd like to turn next to some of your testimony from the past two days about the suspicious order reporting process and I want to start with what I've passed you as DEF-WV-640. Do you recognize this as including the suspicious order regulation from the DEA website?

A. Yes.

MR. SCHMIDT: I don't think we've previously moved this into evidence. I'll go ahead and do that. DEF-WV-640.

THE COURT: Any objection?

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. So, what I'd like to do, Mr. Rannazzisi, is could we

cull out Subsection (b), as in boy? Do you recognize this as the relevant suspicious order regulation?

A. Yes.

Q. And it says the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the administration in his area of suspicious orders when discovered by the registrant. And then here's the language I want to focus on. Suspicious orders include orders of, and can we underline unusual size or highlight it, and then orders, quote, "deviating substantially from a normal pattern", and, quote -- and orders of, quote, "unusual frequency". Do you see that?

A. Yes.

Q. And these three criteria that we've highlighted are the only criteria specified in this regulation, unusual size, deviating substantially from a normal pattern, unusual frequency, correct?

A. That is correct, yes.

Q. You talked over the past couple days about something you refer to as truly suspicious. Is -- when you were talking about something that is truly suspicious, is that something different than a company making a judgment in their view that an order is of unusual size, deviating substantially from a normal pattern, or unusual frequency?

Is there any difference between those two, just yes or no, if you can?

A. No. There's no difference.

Q. In fact -- and there's no greater -- let me try it this way. When you were at DEA you told companies that in terms of interpreting what this language means, in terms of applying it, DEA cannot tell a distributor if an order is suspicious under these criteria, correct?

A. It was up to the distributor to make the decision whether an order is suspicious or not, yes.

Q. And you told them DEA cannot tell a distributor if an order is suspicious, true?

A. Yes, that's true.

Q. It was up to them?

A. Yes.

Q. And in terms of DEA itself, DEA had no internal guidance for what is a suspicious order, correct?

A. There was no guidance except for the regulation, yes.

Q. On your watch as Head of Diversion Control from 2005 to 2015, DEA never had internal guidance as to what constituted a Suspicious Order Monitoring System that complied with regulations, correct?

A. Yes, that is correct.

Q. Are you aware that DEA has proposed to amend this regulation?

A. I believe that -- I don't know what DEA is doing, but I believe that Congress actually codified that regulation.

Q. Do you know if DEA has proposed a rule making process to amend this regulation?

A. I don't know.

Q. Okay. You talked about having responsibility for promulgating regulations, correct?

A. That's correct.

Q. You never amended this regulation on your watch, did you?

A. No, I did not.

Q. Did you ever try internally to add language to this regulation that would go to any of the points you've talked about in your testimony, do not ship, explain why an order is being reported, only report truly suspicious? Did you ever attempt internally to amend the regulation on any of those grounds?

A. No, I did not.

Q. Now, I want to come to an idea I just touched on, which is do you remember talking about explaining -- distributors explaining why suspicious orders were being reported? Do you remember giving --

A. Can you repeat that one more time?

Q. Sure. You gave testimony on several times that you weren't getting explanations for why suspicious orders were

being reported. Do you remember saying that?

A. Yes.

Q. And I'll come back to what the distributors actually did explain, but before I do that, I want to go to this regulation as left unamended by you. There's no language in this regulation saying explain why you consider it to be of unusual size, deviating substantially from a normal pattern, or of unusual frequency, correct?

A. That is correct.

Q. And you never sought to amend the regulation to require such an explanation, correct?

A. We did not amend the regulation, that's correct.

Q. All right. I want to follow up on testimony you had about there not being any policy change at DEA when you came into place and I want to focus on this 2005 to 2008 window, if that's okay.

A. Okay. Yes, sir.

Q. And do you have the understanding that, as the Court has heard through testimony, by 2008 every defendant in this case had a policy in place that involved blocking flagged orders? Do you have that understanding?

A. From my knowledge at DEA?

Q. Yes, sir.

A. Yes.

Q. Okay. And you agree that if an order is blocked the

medicine cannot be diverted?

A. If the order is blocked, the medicine can't go downstream.

Q. And it can't be diverted, correct?

A. That's correct.

Q. And from your time at DEA you can't identify any orders in Huntington or Cabell County that you believed that DEA should have been blocked by one of the defendants but were not, correct?

MR. ACKERMAN: Objection, Your Honor, and this goes to the scope of Mr. Rannazzisi's deposition. The words "West Virginia" don't appear in the deposition transcript, so --

THE COURT: Overruled. This is cross examination. I'll allow it. Go ahead.

THE WITNESS: No, I have not reviewed any documents related to West Virginia.

BY MR. SCHMIDT:

Q. So, let me focus still on this time period when you came in from 2005 through 2008 and even into 2009. Am I correct that before 2006 and 2007 you have no firsthand knowledge about whether the DEA was aware that it had earlier been standard practice in the industry to file Suspicious Order Reports while continuing to ship product? Am I correct you have no firsthand knowledge on that point?

A. Could you -- what do you feel is firsthand knowledge?

Q. Whatever you consider firsthand knowledge. And if it helps to show you your testimony, I can show you your testimony.

A. I have no -- I have no direct knowledge except for what my staff told me.

Q. And I'm not going to ask you about discussions because of hearsay. You've talked about effective controls against diversion; you remember that, right?

A. Yes.

Q. Am I correct that prior to the Fall of 2005 and since 1970, you can't recall any type of document or guidance where the distributors were told to do certain things that were related to maintaining effective controls against diversion?

A. That's correct.

Q. And am I correct you've not watched the testimony in this case to see testimony from individual witnesses at individual companies where they said prior to 2008 if they saw something that they thought was likely to be diverted they would block it? Have you seen that testimony?

A. I have not seen that testimony, no.

Q. Do you know what the practice was prior to 2005 with the defendants in this case when they saw an order that was likely to be diverted?

A. I only know what I was briefed on at the time, yes.

Q. For example, did you review McKesson's Section 55 of this Drug Operation Manual to see that practice of blocking orders that were actually likely to be diverted before 2008 codified in the manual? Have you reviewed the manual to see that?

A. When I was with DEA?

Q. Yes, sir.

A. No, I didn't review the manual but, again, I was briefed on that before the Orders to Show Cause were issued.

Q. Do you remember being briefed on that provision of the manual?

A. I was briefed on the overall -- the overall system before the -- before the Order to Show Cause was issued. I was briefed on the overall system.

Q. That included a portion of McKesson's manual that codified the practice of blocking orders that actually appeared like they were likely to be diverted before 2008?

A. I don't recall the specific provisions that I was briefed on.

Q. Let's look at your 2006 letter, please. Do you recognize this as your September 27, 2006 letter?

A. Yes.

Q. And if we go to Page 2, I want to pick up on a sentence you were asked about.

A. Okay.

Q. In the second paragraph, the first sentence, DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Did you believe that statement to be true when you said it in September of 2006?

A. Yes.

Q. You don't know of any distributor that was blocking suspicious orders instead of shipping them and reporting before 2008, correct?

A. Could you repeat that one more time?

Q. Of course I can. You don't know of any distributor that was blocking suspicious orders instead of shipping them and reporting them before 2008, correct?

A. Blocking suspicious orders before shipping and reporting them? Well, if they were blocking them, they wouldn't be shipping them. So, no, I don't know of anybody.

Q. In place of? Do you know of any distributor that was blocking suspicious orders instead of shipping and reporting them before 2008?

A. I don't believe -- no, I don't, because they were continuing to ship downstream.

Q. Okay. And you don't know whether it's true or false that no distributor blocked suspicious orders before sending them prior to 2006 when you wrote this letter that you

recognize that the overwhelming majority of registered distributors act lawfully, correct?

A. We weren't receiving suspicious orders back then.

Q. Well, I'm going to come to that point. I'm asking you a separate question, sir.

A. Okay.

Q. No distributor blocked suspicious orders before sending them prior to 2006? You don't know if that's true or false, do you?

A. I don't know if it's true or false.

Q. You can't point to any action the DEA took against any of the hundreds of distributors that were reporting and shipping prior to 2006, correct?

A. I don't recall any actions prior to 2006.

Q. You mentioned Michael Mapes several times. He was one of your colleagues at the DEA, correct?

A. Yes.

Q. And, in fact, he was responsible for training diversion investigators when you joined DEA, correct?

A. Yes, he was.

Q. He oversaw the program that trained you as a diversion investigator, correct?

A. Yes.

Q. And you have seen testimony where he said he told the plaintiff lawyers in front of you that DEA accepted

companies shipping and then reporting suspicious orders, correct?

A. I saw what he said.

Q. Yes.

A. It was presented to me in my deposition, but I didn't agree with that.

Q. I understand you don't agree with that, but you had seen his testimony?

A. Yes.

Q. Before it was presented to you, correct?

A. I don't recall seeing his testimony before it was presented to me in deposition, no.

Q. Let's cull up the July 16th, 2020 transcript and I'll show you what I'm talking about and, if I'm misunderstanding what you're saying, you can tell me. Page 210, Line 1 to 7, please.

Do you see where I had the chance to ask you -- Line 1 to 7, please. Did you see that in his testimony that he told plaintiff lawyers, including lawyers in this case, and this is a different case, that DEA accepted companies shipping and then reporting suspicious orders? Did you see that in his testimony? Answer, I saw that in his testimony.

A. Can I see what was done before that?

MR. ACKERMAN: Your Honor --

THE WITNESS: Can I see the page before that, Page

209?

MR. ACKERMAN: Mr. Schmidt, can you give me the date of that deposition again?

MR. SCHMIDT: Yes. It's July 16th, 2020.

THE WITNESS: I don't want this taken out of context, so if I could look at 209, that would be great.

BY MR. SCHMIDT:

Q. My testimony is, do you see that testimony?

MR. ACKERMAN: Your Honor, before we go forward, is that the MDL deposition or is that Mr. Rannazzisi's expert deposition in a different case?

MR. SCHMIDT: It's the Ohio deposition.

MR. ACKERMAN: So, Your Honor, this is -- I need to make a record on this. The defendants filed a motion that said the scope of Mr. Rannazzisi's testimony is limited to information that was in his MDL depositions and we, the plaintiffs, agreed to that and that was the scope of the direct questioning. And when we went outside that scope, defendants objected.

This line of questioning is now concerning something that wasn't in the MDL deposition, but was in a totally separate expert deposition in another case involving the Ohio Attorney General. So, we would object to this line of questioning as outside the scope because cross examination necessarily has to be within the scope of the direct

examination.

MR. SCHMIDT: Two responses, Your Honor. This is within the scope. He testified about there not being a change in policy. He knows there was testimony from his colleagues, the very person who trained him, that there was a change in policy. So, that's an appropriate question that's well within the scope even if we were limited to the scope of his exam, which I don't believe we are. We're with a fact witness who we can't re-call in our case; but even if we were, it's well within the scope.

And as to the point that this is from an expert deposition, yes, it is, but this question is about his knowledge, the expertise he's claiming from being a DEA servant.

I'm not going to ask him about any of his expert opinions in Ohio because I agree those are off limits, but when he made factual statements, or talked about his experience, or talked about his knowledge, it's not a get-out-of-jail-free card where that's not usable. That's sworn testimony. And it's based on his experience, not based on his expert opinions in that case.

THE COURT: Well, this is cross examination and this is a prior statement that appears to be potentially inconsistent and I think it's fair game, Mr. Ackerman, and I'll overrule your objection.

BY MR. SCHMIDT:

Q. Do you remember showing the judge the Diversion Investigators Manual from 1997, Mr. Rannazzisi?

A. Yes.

Q. I want to come back to that. Can we put that up on the screen? It's P-8861, Page 10. And do you still -- if you need a copy, I can give you a second to find it, but I'm going to show you exactly on the screen what we're looking at. It's Page 10 of P-8861. Do you recognize this as the Diversion Investigators Manual?

A. I recognize it as the Diversion Investigators Manual. I don't have it in front of me.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

Q. It's got a cover e-mail that looks like this. That's not going to be it. It's a half page cover e-mail. But I'm going to show it to you on the screen, so only if you need it.

A. Okay.

MR. SCHMIDT: And while we're looking for that, can we go to the next page, please, and highlight the date of this document at the bottom?

BY MR. SCHMIDT:

Q. Tell me when you're ready for me, Mr. Rannazzisi.

A. Here it is. We can just go off the screen. That would

be fine.

Q. Okay. Do you see on Page 11 this Diversion Investigators Manual is dated April 16th, 1996?

A. Yes.

Q. And let's go to the language that you talked about yesterday on the next page and I want to spend a little bit more time on some of that language. Let's start with the first full sentence on the page. It says suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as. Do you see that language?

A. Yes.

Q. And it then lists some of the criteria from -- or all the criteria from the suspicious order regulation?

A. Yes.

Q. Unusual size, unusual frequency, or those deviating from a normal pattern, correct?

A. Yes.

Q. And what this says is that might lead to possible diversion, correct?

A. Yes.

Q. It then goes on to say how the supplier, the distributor, can determine whether something is suspicious, correct?

A. Yes.

Q. It says the supplier can determine whether an order is excessive. Do you see that word excessive?
A. Yes.
Q. By checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. Do you see that?
A. Yes.
Q. And so, that's talking about setting a threshold as a means of identifying suspicious orders, correct?
A. It's one method, yes.
Q. And it's the only method listed here, correct?
A. Yes.
Q. It then says that in the next sentence. If the customer exceeds this threshold, the request should be viewed as suspicious. Do you see that?
A. Yes.
Q. And to be clear, if it's -- well, let me break this down. This is saying that if a distributor sees orders that exceed a threshold they've set for their customers that should be viewed as suspicious, correct?
A. That's what it says, yes.
Q. And that means it should be reported, correct?
A. That means that customers should -- the distributors should do due diligence to make the determination.

Q. It doesn't say due diligence anywhere in here, does it?

A. No, it does not.

Q. If an order is, quote, "viewed as suspicious", should it be reported, yes or no?

A. According to this, yes.

Q. Okay. And then let's look at the next sentence, please. And let me just start on the first two words. It says this activity. Do you see those words, this activity?

A. Yes.

Q. This activity is an order that exceeds the threshold, correct?

A. Yes.

Q. And it says this activity, and I want to focus on the next clause, over extended periods of time. Do you see that language?

A. Yes.

Q. Would lead a reasonable person to believe that controlled substances possibly are being diverted. Do you see that language?

A. Yes.

Q. And so, this is saying if you see this activity, suspicious orders over extended periods of time, that activity over extended periods of time would lead a reasonable person to believe that controlled substances possibly are being diverted, correct?

A. Yes.
Q. Now, there's no specific language in here saying that a registrant should, quote, not fill a suspicious order, correct?
A. I've got to read the rest of that.
Q. Take a moment. This is an important point, sir.
A. Well, it does later on in the paragraph.
Q. And what does it say?
A. As a general practice, investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken.
Q. Okay. So, let's break that down because that's the important point. First of all, it gives us two circumstances for halting orders, correct?
A. Yes.
Q. One is where previous action has been taken against the registrant, correct?
A. That's correct.
Q. And the other is registrants involved in suspected diversion, correct?
A. Yeah.
Q. Those are the two instances where it says that -- where

it talks about voluntarily halting shipments, correct?
A. Yes.
Q. And let's talk about that second one, registrants involved in suspected diversion. Do you see that language?
A. Yes.
Q. This tells us that seeing suspicious orders over extended periods of time would lead a reasonable person to believe that controlled substances are being diverted, correct?
A. That's what it says, yes.
Q. There's no language in here that says that a company should not fill a single suspicious order, correct?
A. I don't think we've ever taken action on a company that filled a single suspicious order.
Q. Okay. And we looked at this language here about -- do you see the reference to excessive in the context of talking about setting thresholds as a trigger for reporting suspicious orders?
A. Yes.
Q. There's no language in here that says Excessive Purchase Reports will not be accepted, correct?
A. It won't have to because Excessive Purchase Reports don't exist in the code or the regulations. Only Suspicious Order Reports.
Q. When this talks about determining if an order is

excessive does it say anywhere in here Excessive Purchase Reports will not be accepted? Does it say that, sir?

A. No. And, in fact, we did receive Excessive Purchase Reports, but that's not a Suspicious Order Report.

Q. You've seen Mr. Mapes' sworn testimony where he said in front of you that the DEA accepted Excessive Purchase Reports as compliant with the Controlled Substances Act at least between 1997 and the distributor briefings; true?

A. No. The first time I saw that was in my deposition in the MDL. It was presented to me.

Q. Okay.

A. And I said during that deposition that I don't recall that.

Q. Okay. But you have seen that testimony from Agent Mapes, correct?

A. In my MDL deposition and I said that I didn't recall him saying that. And during that meeting, I was in and out of that meeting constantly because that was not my meeting. I was there just to make an introduction.

Q. Totally fair. You just know he's testified to that, right?

A. Yeah. After the MDL deposition.

Q. Okay. I want to look at this point we talked about, a change in policy or not a change in policy. What is the purpose of this Diversion Investigators Manual?

A. Diversion Investigators Manual provides guidance to day-to-day operations and what they're supposed to be doing.

Q. What they're supposed to be doing? Okay. You changed this very language we're looking at in the Diversion Investigators Manual, correct?

A. I changed it?

Q. Uh-huh. Did you update the Diversion Investigators Manual on your watch?

A. The Diversion Investigators Manual was updated, yes.

Q. All right. Let's take a look at that.

MR. SCHMIDT: I'm sorry, Your Honor. May I approach? Thank you.

BY MR. SCHMIDT:

Q. So, I've given you DEF-WV-3842. It's a memorandum on the DEA letterhead dated October 27th, 2009 from you with your signature to various people, Special Agents in Charge, Diversion Program Managers, Diversion ASACs, Diversion Group Supervisors, TDS Supervisors. Do you recognize this document with your signature on it?

A. Yes.

MR. SCHMIDT: We'd move this into evidence, Your Honor, DEF-WV-3842.

THE COURT: Any objection?

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. All right. So, let's look at what we -- what this document is doing. The first sentence of this document says the Office of Diversion Control is in the process of rewriting the diversion manual. That's the manual we were just looking at, correct?

A. That's correct.

Q. The purpose of which is to re-focus efforts within the program to ensure continued compliance among the registrant population. Do you see that?

A. Yes.

Q. And that is why you were updating the diversion manual, correct?

A. That and there were other things (unintelligible) --

COURT REPORTER: I'm sorry. Other things --

THE WITNESS: There were other provisions in the manual that needed to be updated because of different changes in law.

BY MR. SCHMIDT:

Q. And then the next paragraph says until such time as the manual is finalized, the attached interim guidelines will be implemented. And then you say it's the responsibility of all Diversion Program Managers and Diversion Group Supervisors to ensure the documented interim guidelines are incorporated into current and future investigations and work

plans upon receipt of this memorandum. Do you see that?

A. What was the question?

Q. Do you see that language?

A. Yes.

Q. And then if you look at the attachment, you did, in fact, attach the interim policy in lieu of diversion manual changes, correct?

A. Yes.

Q. This was an update to the diversion manual policies on your watch, correct?

A. Yes.

Q. All right. Let's look at these changes in the policies on your watch. Can we go to 3, please? And do you see it says suspicious order reporting? Do you see that language at the bottom of -- it's that funny thing where if you look in the lower left corner, I'm going to always be using those numbers.

A. Okay.

Q. So, it's actually Page 2 in the document, but Page 3 in the lower left corner.

A. Yeah. I've got it.

Q. And do you see where it says suspicious order reporting?

A. Yes.

Q. It states OD, that's the Office of Diversion, right?

A. Yes.

Q. In conjunction with CCD, has notified in writing, all distributors of their responsibility to immediately report all, quote, "suspicious orders", quote. Do you see that?

A. Yes.

Q. A suspicious order is an order, which, when received by a registrant and in accordance with 21 CFR 1301.74, that's the regulation you were looking at, correct?

A. Yes.

Q. The registrant determines to be suspicious. Do you see that?

A. Yes.

Q. And then it says the registrant -- and it's bolded and underlined for emphasis -- does not fill the order but reports same to their local DEA Office. Do you see that emphasized language, does not fill the order?

A. Yes.

Q. It then says -- that was new to this interim version of the manual, that bold underscore language, correct?

A. Does not fill?

Q. Yes.

A. It's just -- it's just an update of the previous language.

Q. That language does not appear in the prior manual as applied to a single order, correct?

A. I would have to go back and look.

MR. SCHMIDT: Why don't we -- why don't we help Mr. Rannazzisi out. Could we do a side-by-side and can we put P -- on the left side, could we put P-8861 on the left? If it's possible to switch those so that P-8861 is on the left, please.

And go to Page 12 on the left, please. And if we can blow up that language a little bit.

And then on the right, can we put DEF-WV-3842, Page 3? And if we could blow up that suspicious order reporting.

And let's highlight, if we could, on the bottom does not fill the order, singular.

BY MR. SCHMIDT:

Q. Do you see that language?

A. Yes.

Q. That's new to the 2009 update, correct?

A. That's new to the manual.

Q. Okay. And then the manual, the 2009, goes on to say Excessive Purchase Reports from registrants, reports of unusual size, will no longer be accepted by the DEA, correct?

A. That is correct, yes.

Q. And that bold underline language in the second sentence, will no longer be accepted, it doesn't say they've never been accepted. It says they will no longer be

accepted, correct?

A. Yes. I can give you an explanation, if you would like, why it says that.

Q. And it says any firm still reporting excessive purchases. So you knew firms were doing that, right?

A. Uh-huh.

Q. Will be informed of the OD directive and instructed to immediately report, quote, "suspicious orders", quote. Do you see that?

A. Yes. And the reason that was placed there was because even after we instructed the firms in the letters and even though that we had the face-to-face meetings they were still sending Excessive Purchase Reports and we decided that instead of continuing to receive these Excessive Purchase Reports, which were not Suspicious Order Reports, and we told them those are not Suspicious Order Reports, to just stop sending the Excessive Purchase Reports totally.

Even though they knew that those weren't Excessive Purchase Reports they continued to send them. The only way to stop it is just to tell them to stop it. That's why that provision was put in there.

Q. That language does not appear in the Diversion Investigators Manual from before your tenure, correct?

A. It doesn't appear to appear, yes.

Q. And let's just show exactly what we're looking at in

the old version before, Mr. Rannazzisi. Can you highlight the supplier can determine whether an order is excessive? Starting on the sixth line, the supplier can determine whether the order is excessive. Do you see that?

A. Yes.

Q. Okay. Despite referencing the possibility of an order being excessive before your watch there's no language saying Excessive Purchase Reports will not be accepted, correct?

A. No, but the line above it talks about what suspicious orders are, which is different than excessive purchases.

Q. And then the language you have, Excessive Purchase Reports will no longer be accepted, that doesn't appear in the version of the manual before your time; is that right?

A. That's right.

Q. And then this language about does not fill the single order does not appear in the version of the manual before your watch, correct?

A. No, it does not.

Q. And what the version of the manual before your watch refers to is -- let's highlight starting on the midpoint, this activity, refers to this activity, suspicious orders, over extended periods of time, correct?

A. That's a vague statement, over extended periods of time. That could be a couple of weeks. It could be a month.

Q. And you took that language out in your version, correct?

A. Yes. It was -- that was the language that was removed, yes.

Q. And both of those were changes, right, to the language?

A. Yes. It was because we were reemphasizing suspicious orders because they weren't being followed.

Q. One --

A. The suspicious order guidelines were not being followed, so we reemphasized it in the manual.

Q. One change in the manual is you removed any linkage between determining whether an order is excessive and exceeding a threshold being suspicious. You removed that linkage, correct?

A. That's no longer in the 2010 manual, yes.

Q. And instead you changed it to say we don't accept these policies any longer, correct; these reports, I'm sorry, any longer, correct?

A. Yes. We said that.

Q. And instead of talking about suspicious orders over extended periods of time leading a reasonable person to believe that controlled substances possibly are being diverted, you changed it to say the registrant does not fill the order, singular, correct?

A. That's correct.

Q. Okay.

A. Which is consistent with the letters that we sent. Which is consistent with *Southwood*. Which is consistent with the distributor initiative briefings, which happened way before 2010.

Q. Okay. I want to talk about just what you just mentioned, *Southwood*.

A. Okay.

Q. And this is going to seem like diversion, but it's not. You remember -- you're familiar with the *Masters Pharmaceutical* case, correct?

A. Yes.

Q. And that was a case that was being adjudicated while you were still at the DEA, correct?

A. I think the final decision came out after I was at DEA but, yes, I was there during *Masters*.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes, you may.

MR. SCHMIDT: Thank you.

BY MR. SCHMIDT:

Q. I've passed you what I've marked as DEF-WV-2578. Do you see that this is a Federal Register entry from September 5th, 2015?

A. Yes.

Q. And just to be fair, the Court has seen the DC Circuit

appeal that followed this decision. That came after your watch. You were still at the DEA, though, on September 15th, 2015, correct?

A. Yes, but when you talked about the *Masters* decision, I was still thinking about the appellate decision.

Q. And that's why I wanted to be fair to you.

MR. ACKERMAN: Your Honor, I'm going to interpose a scope objection to the extent this was not at all mentioned or questioned in the MDL deposition.

MR. SCHMIDT: Your Honor, I don't think they get to bring a witness and ask him questions, including questions that were demonstrably outside the MDL over objection, and then shut it down on that basis.

THE COURT: Overruled.

BY MR. SCHMIDT:

Q. So, just to go back to this decision and to orient the Court to what we're talking to in that distinction between the DC Circuit decision and this decision, if you look at Page 85 of the decision, the last page, this is the decision from the DEA itself, Chuck Rosenberg, the Acting Administrator of the DEA, dated September 18th, 2018. Do you see that?

A. Yes.

Q. That came while you were still at DEA, correct?

A. Yes.

Q. And then later, as the Court has seen, this decision was appealed and that was after you left, the DC Circuit decision?

A. Yes.

Q. Okay. So, I'll focus on this one for now.

MR. SCHMIDT: And I'll move it into evidence, DEF-WV-2578.

THE COURT: Any objection?

MR. ACKERMAN: I will preserve our scope objection, but I suspect you know I know how you will rule on that.

THE COURT: Okay.

MR. ACKERMAN: Can I just ask for a standing objection on scope matters?

THE COURT: Yes, you can.

MR. ACKERMAN: All right. Thank you. So that will be preserved for the record.

THE COURT: Okay.

MR. SCHMIDT: And, of course, we have no objection to any standing objections and would ask for the same courtesy to make things go fast.

BY MR. SCHMIDT:

Q. All right. Let's look at Page --

MR. SCHMIDT: Sorry. Is this admitted, Your Honor?

THE COURT: Yes. It's admitted. It's admitted.

BY MR. SCHMIDT:

Q. Could we go to Page 59 of the decision and let's cull out the first several lines in the upper left-hand corner. Two points on this decision.

First of all, do you see that in the second line here there's reference to the Rannazzisi letters?

A. Okay.

Q. Do you see that reference?

A. Yes.

Q. And you understand that the DEA is referencing your letters from the distributor initiative, 2006 and 2007, correct?

A. I -- like I said, it's been a long time since I've seen this and, quite frankly, I have no idea what is in there. That was a long --

Q. Let's look at what they say just to answer that question. Do you see there's a reference to a 2007 letter? Do you see that?

A. Yes.

Q. And you wrote a letter on December 27th, 2007, correct?

A. Yes, I did.

Q. And that letter contained the very language on Page 2 that this DEA opinion quotes as appearing on Page 2, correct?

A. Yes.

Q. And then they quote more and that language also is the next sentence from your letter, also on Page 2, in December, 2007?

A. Could I see --

Q. Yes, of course. That's the end of the quote of your -- of your letter. Do you see them quoting another sentence from your letter in December of 2007?

A. Okay, I see it.

Q. And then let's look at what they say about the letter. They say contrary to the ALJ's understanding -- you understand an ALJ is an administrative law judge, right?

A. Yes, I do.

Q. This simply is not language that manifests an intent to bind the agency. Do you see that language?

A. Yes.

Q. Do you remember giving testimony yesterday that your letters were intended to be official guidance from the DEA?

A. Yes.

Q. Do you know that the Administrator, the acting Administrator of the DEA, had concluded that this simply, with respect to the 2007 letter, is not language that manifests an intent to bind the agency? Did you know about that language in this decision before I showed it to you just now?

A. No. I don't recall that language.

Q. Let's go to the next sentence. Nor is the 2006 letter -- do you remember showing the Court the 2006 letter that you sent to all registrants?

A. Yes.

Q. Nor is the 2006 letter fairly read as manifesting an intent to bind the agency. Do you see that language?

A. Yes.

Q. And if we look further down, do you see that they actually quote Page 2, your 2006 Dear Registrant letter?

A. Okay.

Q. Do you see that?

A. So, you're looking at Page --

Q. I'm looking at this paragraph on the screen where they actually quote Page 2 of your 2006 Dear Registrant letter.

A. Yes.

Q. And when you testified yesterday that your letters were official guidance of the DEA, did you know that while you were there the Acting Administrator of the DEA said nor is your 2006 letter fairly read as manifesting an intent to bind the agency? Did you know that, sir?

A. No, I didn't. This was, again, the end of my tenure. It was September when the order was released.

Q. All right. Let's look further up this page. I'm going to ask you about one other point.

A review of the letters shows that they were not intended -- and we're talking about the Rannazzisi letters here. Do you see that? A review of the letters shows that they were not intended to have binding effect, but were simply warning letters. Did you know about that language before I showed it to you just now?

A. No, but those letters didn't occur under this -- that Acting Administrator. They occurred under Karen Tandy and Michelle Leonhart, who were Senate confirmed Administrators, not a -- an Acting Administrator.

Q. Go back to Page 85, please, and there you see this title that you just pointed out, Acting Administrator; do you see that?

A. Yes. Acting administrator. Not Senate confirmed. Acting Administrator.

Q. Was he in charge of the DEA at this time?

A. Yes.

Q. Was he your boss at this time?

A. Yes, he was.

Q. And I take it if you didn't know about this language you never took a public position while you were at the DEA disagreeing with this language?

A. Well, again, in September, I was on my way out. They had already replaced me at that point in time. So, no. But during my tenure, when I was in charge, those letters were

guidance. The Administrators, the two Administrators, knew about those letters and had no problem with those -- with those letters issued as guidance.

MR. SCHMIDT: And I'll move to strike his testimony about the thoughts of other -- other people.

THE WITNESS: Well, they were based on -- I'm sorry.

MR. ACKERMAN: We oppose that, Your Honor.

THE COURT: Well, I'll sustain that one.

MR. ACKERMAN: I'm sorry.

THE COURT: I'll grant the motion to strike that portion of his testimony.

BY MR. SCHMIDT:

Q. Now, I mentioned *Southwood*. Do you remember that?

A. Yes.

Q. *Southwood* talked about the due diligence requirement, right?

A. Yes.

Q. And that the idea of the due diligence requirement is -- it requires a registrant to first determine whether an order is suspicious and, if so, take appropriate action to dispel the suspicion before fulfilling the order, correct?

A. Yes.

Q. And that's this do not ship idea, right?

A. That's the do not ship.

Q. Okay. Let's look at what this opinion from the Head of the DEA says about *Southwood*. Could we go to Page 60? And *Southwood*, to orient us, was in 2007, correct?

A. The *Southwood* opinion was in 2007.

Q. Okay. Let's look at what they say in the upper right corner, the first paragraph there. And we see there's some case law citation here. I'm going to go to the sentence right after that begins with "moreover" and tell me when you're there. Do you see where I'm referencing?

A. Yes.

Q. Okay. It says because the due diligence rule we've been discussing was announced in an adjudication, and then it goes on to say respondent was free to argue why the rule should not be applied in this matter as it was here in this matter. Do you see that?

A. Yes.

Q. And Mr. Reynolds has helpfully underlined this rule about due diligence being announced in an adjudication. Do you see that?

A. Yes.

Q. And you understand, as we see in the next sentence, that the adjudication in this opinion is saying that the due diligence decision was announced in the *Southwood* decision, correct?

A. I'm sorry. Please repeat that. I'm trying to look at

this and listen at the same time.

Q. Sure, no problem. When it says the due diligence rule was announced in an adjudication, do you see that?

A. Yes.

Q. That reference to an adjudication?

A. Yes.

Q. You understand that the adjudication being referenced is a *Southwood* decision from 2007, correct?

A. Yes.

Q. According to this, that's where this due diligence rule was announced, correct?

A. Well, it was announced in a final order, yes, at that point in time.

Q. And, in fact, you pointed distributors to the *Southwood* decision to provide them with more information about your understanding and your interpretation of the Controlled Substances Act in your second letter in 2007, correct?

A. That's correct, December of 2007.

Q. All right. Let's look at one more exhibit in this regard.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. This is a decision -- I'm sorry. This is the wrong one. Can I grab that back? This is the DC Circuit *Masters*

decision. I didn't mean to hand you that. I'm happy to talk about it, but it's after your time, so I didn't mean to give you that.

May I approach again, your Honor?

THE COURT: Yes.

MR. SCHMIDT: So, Your Honor, what I've passed the witness is an exhibit marked DEF-WV-2261. We used this with Mr. Rafalski and, at the time, I think what I proposed to the Court is that the Court could take judicial notice of it, but it didn't make sense to move it in as an exhibit yesterday, we took the decision, as an exhibit. So, I will go ahead and move this into evidence.

THE COURT: Any objection, Mr. Ackerman?

MR. ACKERMAN: Yes. I think the decision that was taken as an exhibit was an ALJ decision and, therefore, was a public record and taken as evidences of notice. I don't think we would agree that a court decision is appropriate as evidence.

THE COURT: Well, what about it, Mr. Schmidt?

MR. SCHMIDT: I think it's a government record. It is a literal definition of a governmental record and I think there's --

THE COURT: Well, I can take judicial notice.

MR. SCHMIDT: And you can take judicial notice.

THE COURT: It's admitted, Mr. Ackerman.

MR. ACKERMAN: Your Honor, can I clarify something for the record because --

THE COURT: Mr. Schmidt, let's --

MR. SCHMIDT: Sorry.

MR. ACKERMAN: I think he was just asking Mr. Rannazzisi if he needed water.

I just wanted to clarify something for the record because this is an issue that has come up several times. I think it came up with direct sales. I think it came up other times in this litigation. If the Court is going to be accepting -- there were instances where the Court did not accept judicial decisions as evidence or exhibits in this case.

And so, if that -- if the Court is going to adopt a different practice at this time, that's perfectly within the Court's discretion. I just want to make it clear because I know this is an issue likely in deposition designation exhibits to objections and elsewhere.

THE COURT: Well, I'm not sure I understand why there's an issue about this.

MR. ACKERMAN: So, the decision that we moved in yesterday was *Southwood Pharmaceuticals*, which was from the DEA website, and it was in the Federal Register like this *Masters* decision. I understand.

These are court decisions. They're not -- they can't

be admitted for the truth. I -- I'm certainly not going to question that a judge is not reliable, but we have heard from defendants over and over again in this trial that judicial opinions aren't evidence.

So, I don't understand the purpose for which they're being offered and I believe the Court has rejected earlier attempts to put judicial opinions in as evidence.

MR. SCHMIDT: And Mr. Ackerman is right. We have objected. We've taken the position that they're notice with change. And the reason I move this in now and not before is yesterday the Court admitted the *Southwood* decision. Our view is that's exactly the same principle subject to judicial notice.

Frankly, I don't think we have a strong view either way, but if some key opinions are going in the record, we think this is a key opinion that should go in the record. I think it's a little bit of an academic dispute and, on my part, is prompted only by *Southwood* going in yesterday and I'm wanting to make sure that the Court has access readily in an easy form in the record to what we're talking about.

But I do think the point is right. The Court can take notice. So, whichever the easiest way to deal with it is, I'm fine with proceeding. It's something that's before the Court. I think the Court has taken judicial notice of this decision. I don't think any of these materials need to be

in the record in terms of the *Southwood* decision yesterday, but if we are admitting them, it makes sense to treat them the same.

THE COURT: Well, what -- what is the purpose that it's admitted? It's not coming in for the -- just tell me what the -- what the purpose of it as evidence is.

MR. SCHMIDT: The purpose of it as evidence is it documents sworn testimony in the case from Mr. Rannazzisi's colleagues on his watch while he was at DEA on relevant points in this litigation.

THE COURT: Well, you could use it as a basis to ask him about that without admitting it, couldn't you?

MR. SCHMIDT: Yes, but I think if we're going to admit some decisions like *Southwood* from yesterday, the better course is to admit this.

THE COURT: Mr. Ackerman?

MR. ACKERMAN: The distinction, Your Honor, that we have made is that we admitted *Southwood* as notice to the defendants. This is not being offered for notice. It's being offered essentially for the truth of the matter asserted therein.

MR. SCHMIDT: *Southwood* was not admitted under a limited basis.

MR. ACKERMAN: And it was a public record of the DEA, not of a -- this is --

MR. SCHMIDT: A public record of the United States Judiciary, Article III of the Constitution.

MR. ACKERMAN: I'm going back to my rules, Your Honor. 803(8) says a record or statement of public office, and I don't know whether the Judiciary in and of itself is a public office. I am just going to say that's what the rule says.

THE COURT: I don't understand why there's a big argument about this when it's a matter that -- a public record that the Court could take judicial notice of. Why does it have to be admitted as evidence or not as admitted as evidence?

MR. SCHMIDT: That's what I was going to say. With that statement from the Court, I'll just question on it and I'll -- I'll move on.

BY MR. SCHMIDT:

Q. You have in front of you DEF-WV-2261.

A. Yes.

Q. And do you understand that this is a decision involving the United States while you were at DEA from the Eastern District of Michigan in 2012?

A. Yes.

Q. And do you have the understanding from seeing this decision before, and I can point you to a specific portion of the opinion, that it reflects testimony from people in

your office, Kyle Wright, Michael Mapes, James Rafalski, under your supervision as Head of the Office of Diversion Control?

A. I seem to remember Kyle Wright. I didn't know Mike Mapes was involved in this.

Q. Okay. And let me actually correct. I'm not sure if he gave testimony, but he's quoted in the opinion. So, let's look at Page 6 of the opinion, please. If we could cull out the third paragraph, please.

It says the government offered testimony that the DEA sought to expand drug wholesalers' obligations by a policy change in 2006 and 2007, although there was never a change to the regulations.

THE COURT: Mr. Ackerman?

MR. ACKERMAN: Objection, Your Honor, and this is the problem that we get into. This is several levels of hearsay because this is now the Court saying that the government said something. We don't have any access to the record in this case. If there was testimony by the government, it's something that we can assess, but at this point, we're now cross examining based on the two or three levels of hearsay.

THE COURT: He's offering this as evidence. If I understand what's going on here, he's offering -- he's using it as a good faith basis to cross-examine the witness and

it's perfectly proper for that purpose.

MR. SCHMIDT: And just for the record, you do have the testimony from this case. We've used it in depositions with Mr. Rafalski.

THE COURT: Overruled. You can go ahead, Mr. Schmidt.

BY MR. SCHMIDT:

Q. Do you see this language about testimony from government officials that the DEA sought to expand drug wholesalers' obligations by a policy change in 2006 and 2007, although there was never a change to the regulations? Do you see that?

A. I see that, yes.

Q. And the point about there was never a change to the regulations, that's true, right?

A. There was not a change to the regulations, no.

Q. And whatever testimony was offered in this case from DEA officials came from DEA officials you supervised, correct?

A. Well, if it's Kyle Wright, yes. He was under my supervision.

Q. And, in fact, just so we're clear, at one point, you were going to give testimony in this case, correct, but because of a kind of timing issue as to when your disclosure was made, you weren't able to give testimony, correct?

A. That's correct.

Q. Okay. One of the changes -- I think you were going to give expert testimony, correct?

A. I was going to give testimony on the suspicious order monitoring requirements.

Q. Okay. One of the changes in interpretation by the DEA concerned the circumstances under which a distributor should suspend shipments to a customer if it identified the customer -- if it identified an order as suspicious. Do you see that?

A. Yes.

Q. And that's the do not ship policy you understand being referenced there?

A. Yes.

Q. That change in policy apparently prompted concern within the DEA compliance sectors that confusion would result since the prior report-only policy had been in place for 35 years and then it refers to DEA personnel began to conduct distributor briefings to familiarize drug wholesalers with the new policy. Do you see that?

A. Yes.

Q. And you understand from the time period that those distributor briefings are the same ones we've been talking about throughout your testimony, correct?

A. Yes.

Q. Goes on to say Kyle Wright, who you supervised, it says DEA began to conduct distributor briefings to -- I'm sorry. Kyle Wright, the Unit Chief of the E-commerce section at the Office of Diversion Control at the DEA Headquarters in Washington, D.C. in 2006 and 2007, testified that he played an important role in developing the briefings. Do you see that?

A. Yes.

Q. Is that true?

A. Yes.

Q. Let's go to the next paragraph. In all events, Wright testified that the DEA was aware that it was standard practice in the industry to file Suspicious Order Reports while continuing to ship products, and that practice had been approved by the DEA. Do you see that?

A. Yes.

Q. Do you recall me asking you yesterday about the fact that there was a window, I think, between 19 -- I'm going to get the years wrong, is it '88 and 2005, where you didn't deal with distributors? Do you remember that?

A. Yes.

Q. Mr. Wright was dealing with distributors before 2005, correct?

A. Yes.

Q. And then here's where I might have gotten tripped up.

Let's go to the next paragraph, please. In the second sentence, it says Wright's supervisor, Michael Mapes, told distributors at the DEA's Pharmaceutical Industry Conference on September 11th, 2007 that the DEA's new interpretation of the suspicious order regulation was that distributors should suspend shipments if they routinely report suspicious orders with reason to believe they are destined for the illicit market. Do you see that?

A. I see that.

Q. Did you attend that conference with Mr. Mapes?

A. No, I did not.

Q. Did you issue any public statements disagreeing with this decision when it came out in 2012 on your watch?

A. No, I did not.

Q. I want to go back to reports that were made before 2008 and you talked about that term "Excessive Purchase Reports"; do you recall that?

A. Yes.

Q. Do you know that McKesson believed it was making Suspicious Order Reports before that period?

A. Yes.

Q. And let's look at what we're -- let's show the judge what we're talking about.

A. Suspicious or excessive?

Q. Suspicious.

A. I don't know if -- what McKesson believed or what they didn't believe, to be honest with you.

Q. Okay, fair enough. They told the DEA they were making suspicious reports, correct?

A. I'm not aware of them telling the DEA that they made suspicious reports.

Q. Okay. Do you have that massive set of reports --

A. Yes.

Q. -- 42747 in front of you?

A. Yes.

Q. And if we go to the second page of that document, and if we look at the heading where it says "McKesson Corporation".

A. Okay.

Q. Do you see right under there it says Monthly Controlled Substance Order Report? Do you see that?

A. Yes.

Q. Okay. And then let's look down at this language here and this is what I want to focus on. Pursuant to CFR 21 Section 1301.74(B). Do you see that?

A. Yes.

Q. Is that the regulation we were looking at that is the suspicious order regulation?

A. Yes.

Q. So, they say pursuant to the suspicious order

regulation we are sending a copy of the Monthly Controlled Substance Order Report for September, '09. Do you see that?

A. Yes.

Q. And then do you remember saying that they never explained why --

A. Yes.

Q. -- they were flagging the orders?

A. Uh-huh.

Q. Let's look at the explanation. It says this report reflects purchases from customers for Schedules II-V, controlled substances which exceed the item monthly average for the class of trade. Do you see that?

A. Yes.

Q. And remember the Diversion Investigators Manual we've looked at that talked about exceeding thresholds?

A. Yes.

Q. This is telling DEA that the way these are identified is they exceed the item monthly average for the class of trade, correct?

A. That's what it says, but that's still not a suspicious order.

Q. If we go on, it says a listing of the parameters used are available upon request. Do you see that?

A. Yes.

Q. Were they ever requested, to your knowledge? Do you

know?

A. I don't know. But, again, this is not a suspicious order. First of all, this is monthly. It's supposed to be done when discovered. And you're supposed to have a description of why it's suspicious, not just that it breached threshold.

You're supposed to talk about the pharmacy. Explain why this pharmacy is doing something suspicious. Not just -- not just, oh, they were above threshold. That means nothing to us.

Q. Let's go back to DEF-WV-640. Do you remember this language in the regulation?

A. Yes.

Q. Where does it say in there you've got to tell us about the pharmacy or why you say it's suspicious?

A. It doesn't. It says it in the letters that we wrote providing guidance.

Q. Is there a letter you wrote that says you need to tell us information about this pharmacy?

A. It says that you have to explain why an order is suspicious. Just being over threshold is not suspicious.

Q. When did you write that letter?

A. I think 2006 and -- one of the 2006 or 2007 letters, one of those letters has it. It was also described in the distributor briefings.

Q. Which you didn't attend?

A. That I didn't attend, that's exactly right.

Q. I'll come back to that. Let's go back to the report.

A. Okay.

Q. Sorry. 42747, Page 2, please, back to the report that you looked at for counsel for the plaintiffs.

A. Yes.

Q. And I want to focus again on this language, a listing of parameters used are available upon request. Do you see that?

A. Yes.

Q. Do you know how many times during audits, registrations, otherwise, DEA officials looked at the parameters that were used to determine whether this report that McKesson was making pursuant to the suspicious order regulation, how those worked? Do you know how many times DEA agents looked at those?

A. No, sir, I don't.

Q. All right. Let's go back to DEF-WV-1549. Just to be clear, could we go back to 42747? And I just want to be absolutely clear for the record on this in case I didn't get it.

If we could highlight that language pursuant to 21 C. F. R. 1301.74(B).

Do you see that language?

A. Yes.

Q. Let's go back to DEF-WV-640. This is the suspicious order regulation, 1301.74(B), that we've been talking about that McKesson told the DEA was the basis for it making those reports, correct?

A. Yes.

Q. Okay. So, let's look at the letter that we talked about a little bit yesterday. I want to finish up with this letter from January 23rd, 2006, the DEA memo to you from Mr. Mapes, dated -- Bates stamped -- exhibit stamped DEF-WV-1549. Do you remember talking about this letter?

A. Yes. I'm trying to find it.

Q. And if we go to the second page, I want to just blow up the pharmacies being discussed here.

A. Yes.

Q. And you recall we talked a little bit about these six pharmacies that the DEA identified based on ARCOS data, correct?

A. That's correct.

Q. And they were identifying generic and branded hydrocodone sales, correct?

A. I'm sorry. Who was --

Q. The DEA. These numbers included generic and branded hydrocodone numbers, correct?

A. Yes.

Q. And that came from the ARCOS data that McKesson reported to the DEA, correct?

A. Yes.

Q. McKesson was reporting both generic data and branded data, correct?

A. Yes.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've passed you something marked MC-WV-2143 and let's go to the second page. Do you see that this is the type of DU45 report that you said you had seen at the DEA?

A. I believe I saw this report at one point in time, yes.

Q. Okay. Let's look at what it says.

MR. SCHMIDT: I'll move it into evidence on that basis, Your Honor.

THE COURT: Any objection?

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. If we look at the top, do you see where it says Daily Controlled Substance Suspicious Purchase Report? Do you see it refers to a daily report?

A. Yes.

Q. And if we look in the upper left-hand corner, it gives

us the date -- sorry. It gives us the date that this particular report was run, November 25th. Do you see that?

A. Yes. And then if we look down, it has reports from earlier dates included.

MR. SCHMIDT: Can you take that down?

BY MR. SCHMIDT:

Q. Going all the way back to November 7th. Do you see that?

A. Yes.

Q. And if you look at that language we looked at in the other document right here, do you see that it again references the suspicious order regulation of 21 CFR 1301.74(B)?

A. Yes.

Q. Do you see it says we are sending a copy of the Daily Controlled Substance Suspicious Purchase Report for November 25th, 2005?

A. Yes.

Q. And that it again says we picked it based on exceeding the item monthly average listing the parameters used are available upon request. Do you see that?

A. Yes.

Q. All right. Let's see if we can put on the left-hand side of the screen DEF-WV-1549 and on the right-hand side of the screen the document we currently have up.

And what I would like to do on the left side is on Page 2. So, just to orient us, on the left side, we have the memo you received in January of 2006 reflecting the discussion with McKesson, correct?

A. Say that again.

Q. On the left-hand side we have the memo you received in January, 2006 reflecting the discussion with McKesson?

A. Yes.

Q. And it lists the six pharmacies that were raised with McKesson at that January meeting?

A. Yes.

Q. Let's look at the first one of those pharmacies.

MR. SCHMIDT: Could you highlight on the left AccuMed just down at the bottom?

BY MR. SCHMIDT:

Q. Do you see AccuMed at the bottom of the memo as one of the six pharmacies that was discussed?

A. Yes.

Q. And do you see on the right, if we go to Page -- I'm sorry. I think I skipped us ahead.

MR. SCHMIDT: Just to make it easier, could you highlight MediPharm?

BY MR. SCHMIDT:

Q. Do you see MediPharm is one of the pharmacies that was discussed in the January meeting with McKesson?

A. Yes.

Q. If we look on the right, do you see that this is, according to the document at least, a Daily Controlled Substance Suspicious Purchase Report for MediPharm from November of 2005? Do you see that?

A. Yes.

Q. Okay. And if we look down on the form --

MR. SCHMIDT: Can we go to Page 8, please? On the right. I'm sorry. Let's go to the next one.

BY MR. SCHMIDT:

Q. Do you see that Page 8 is AccuMed? Do you see that?

A. Yes.

Q. And do you see that AccuMed is another one of the pharmacies listed in your letter?

A. Yes.

Q. And if we take down that AccuMed cull-out, do you see that under the AccuMed listing there are listings for a product called Norco, which is a branded prescription opioid? Do you see that? It's a little bit hard to read, but do you see that reference to the branded products?

A. Yes.

Q. And then there's a reference below to generic hydrocodone, correct?

A. Yes.

Q. And these reports that McKesson was making pursuant to

the suspicious order regulation included branded products and generic products, correct?

A. Yes.

Q. All right. And just -- we'll do this as quickly as possible.

MR. SCHMIDT: Could we put up -- we've done MediPharm. We've done AccuMed. Could we put up Page 5 on the right?

BY MR. SCHMIDT:

Q. Do you see that this is Bi-Wise report on Page 5?

A. Yes.

Q. And do you see Bi-Wise is another one of the six pharmacies on Page -- on your January memo?

A. Yes.

MR. SCHMIDT: Let's put up Page 21 on the right.

BY MR. SCHMIDT:

Q. Do you see that this is of Avee Pharmacy with reports made pursuant to the suspicious order regulation on the right, Page 21?

A. Okay.

Q. And Avee is another pharmacy mentioned in your memo in January, two months later, correct?

A. Yes.

Q. Let's go to Page 25. Do you see that there's Universal Rx on the right with reports pursuant to the suspicious

order regulation?

A. Yes.

Q. And do you see that on the left that's another one of the pharmacies mentioned? Do you see that?

A. Yes.

Q. And last one, Page 48 on the right, United Prescription Services, also reports from November, 2005. Do you see that?

A. Yes.

Q. And they're also one of the pharmacies discussed on the left. Do you see that?

A. Yes.

Q. And so we know from looking at this that McKesson's data as it provided it to the DEA -- and ARCOS identified generic and branded data, correct?

A. Yes. It looks that way, yes.

Q. And in these reports made pursuant to the suspicious order regulation, they've identified generic and branded data, correct?

A. Well, these reports aren't made pursuant to suspicious order. They weren't reported as discovered. Some of these reports -- if you go by the fax sheet here, some of these reports were three, four days after the fax sheet. Some of these reports happened -- the fax sheet is dated 1/28. Some of these reports are -- or 11/28. Some of these reports are

after 11/29. So, if the fax sheet is dated 11/28, how could they possibly be reported the day after the fax was actually faxed?

Q. If you flip through that document, do you see there are multiple fax sheets in there?

A. No. I didn't see multiple fax sheets. Okay. I found one. But still --

Q. Let me address your other point, if I could, Mr. Rannazzisi.

A. Yeah.

Q. Did you know these were rolling reports, so that when they made the daily report, they provide the previous reports made for that pharmacy in a month? Do you know whether that was the case or not?

A. No. I don't know whether that was the case.

Q. Let me go back to my question and let's cull out this language pursuant to CFR Section 1301.74(B), right?

A. Yeah.

Q. McKesson said it was providing DEA with reports pursuant to the suspicious order regulation that covered both generic and branded opioids, correct?

A. It looks that way, yes, in these reports, yes.

Q. Now, I touched yesterday on changes McKesson made to its suspicious order monitoring policy in response to some of these discussions in 2005 and 2006 with the DEA about

these pharmacies in Florida. Do you remember touching on that briefly yesterday afternoon?

A. Could you repeat the question, please?

Q. Sure. And why don't I just go to the meat of it. Are you aware that following discussions with the DEA in 2005 and 2006, McKesson twice updated its policies regarding suspicious order monitoring?

A. Yes. I was told that they did their suspicious order monitoring, yes.

Q. Let's go ahead. I'm going to pass out Exhibit DEF-WV-1527.

MR. SCHMIDT: May I approach with that, Your Honor?

BY MR. SCHMIDT:

Q. And this is a letter on the cover written for -- from counsel for McKesson, June 12th, 2007, to Linden Barber, Office of Chief Counsel at the Drug Enforcement Administration. You know Mr. Barber, correct?

A. Yes, I do.

Q. He was a former colleague of yours at the DEA, correct?

A. Yes.

Q. And if we look down, he says I have attached a copy of the following information: Amendment to the McKesson DC Operations Manual describing the standard operating procedures for the lifestyle Drug Monitoring Program and

then a PowerPoint presentation on that program. Do you see that?

A. Yes.

Q. Is that one of the policies that you were told, one of the policy changes McKesson made following these discussions about these pharmacies in this 2005, 2006, 2007 time period?

A. I can't tell you exactly, but I was told that they changed their -- their Suspicious Order Monitoring Program policies, but I -- I can't remember what I was told.

Q. Okay. So, if we go --

MR. SCHMIDT: I'll move this into -- into evidence. It's on the stipulation.

THE COURT: Any objection?

MR. ACKERMAN: No objection, Your Honor.

THE COURT: All right. It's admitted.

MR. SCHMIDT: May I confer for just one moment?

(Pause)

BY MR. SCHMIDT:

Q. Do you see that if we go to Page 3 of this document there actually is a copy of the Lifestyle Drug Monitoring Program being referenced? Do you see that?

A. Yes.

Q. And then if you go to Page 10 of the document, there's a copy of those PowerPoint slides from Mr. Walker, Senior Vice President Distribution Operations that's referenced?

A. Yes.

Q. Did you ever review those materials when you were at DEA?

A. No.

Q. Are you aware of anyone raising concerns about this policy when it was sent to your colleagues at DEA?

A. I -- I'm sure they would have had -- they would have had concerns about it, but it wasn't brought to my attention.

Q. Are there any you can point me to that you know about factually?

A. That was told to me? No.

MR. SCHMIDT: And then one more document in this area and then this may be a good time for a break, Your Honor.

May I approach again?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. Are you aware that in 2008 McKesson adopted a policy called the Controlled Substance Monitoring Program?

A. Yes.

Q. And this document is in evidence, McKesson West Virginia 397. Are you aware that Don Walker, the person we just spoke about from McKesson, came in and gave a presentation on the Controlled Substance Monitoring Program

and provided a copy of that policy to your colleagues at the DEA?

A. No, I'm not aware of that.

Q. Okay.

A. I mean, I'm sure I was told about it, but I can't give you any information about that meeting.

Q. There's no objections you can tell me or concerns that anyone at DEA raised in response to the presentation or the policy, correct?

MR. ACKERMAN: To his knowledge, right?

BY MR. SCHMIDT:

Q. To your knowledge, of course?

A. To my knowledge, no.

MR. SCHMIDT: And then I can stop here or I can do two more minutes, Your Honor. Up to the Court. Probably like five more minutes.

THE COURT: I think this a good place to stop, Mr. Schmidt. We'll be in recess for 10 to 15 minutes.

(Recess taken)

(Proceedings resumed at 10:30 a.m. as follows:)

MR. SCHMIDT: May I proceed, Your Honor?

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, are you good to proceed?

A. Yes, sir.

Q. Thank you, sir. I'd like to continue with one more

point on McKesson.

Let's take a look at the 2008 Settlement Agreement that you talked about with counsel, P-23736. Tell me when you're ready to testify about that.

A. You can go ahead.

Q. Do you recall being asked yesterday about this agreement covering Lakeland, Landover, Conroe, and Denver in terms of those distribution centers?

A. Yes.

Q. Are you aware that none of those distribution centers regularly service Huntington and Cabell County?

A. I -- that I don't know.

Q. Okay. Fair enough. Do you know that the Washington Court House distribution center does regularly service Huntington and Cabell County?

A. Again, if you're asking me back then, I did not know.

Q. Okay. You understand that Washington Court House isn't mentioned in this agreement?

A. I don't believe Washington Court House is mentioned.

Q. You talked about yesterday about how many distribution centers the distributors have. How many does McKesson have?

A. I believe from yesterday 27, 26.

Q. Okay. Let's take 26. Four out of 26 -- when you gave testimony yesterday about this, whether this was or was not a systemic issue, the distribution centers covered by this

agreement are less than 20 percent of the 26 distribution centers you just referenced; correct?

A. We don't look at it that way.

Q. Okay.

A. The way --

Q. Am I right or am I not?

A. 20 percent, but that's a lot of diversion occurring. 20 percent -- these are big facilities that treat a lot of pharmacies, distributes to a lot of pharmacies.

Q. Okay. Let's go to the second page. Just so we have it, you understand that this agreement contains no admission or concession; correct?

A. Yes.

Q. Let's go to -- well, actually, before I go on in this, there was no immediate -- I believe you testified to this. There was no Immediate Suspension Order issued by the DEA leading up to this Settlement Agreement; correct?

A. I'd have to go back and look, but I don't recall -- I don't recall an Immediate Suspension Order. There may have been. I just don't recall.

Q. Okay.

A. I know there was Orders to Show Cause. There were at least four orders -- or three Orders to Show Cause.

Q. And we saw those and we see those referenced in the agreement; correct?

A. Yes.

Q. And there's no reference and no recollection you have of an Immediate Suspension Order; correct?

A. No, not that I -- I don't recall an Immediate Suspension Order. I just recall the Orders to Show Cause.

Q. And DEA would issue an Immediate Suspension Order when you were at DEA if there was an imminent danger to the public health or safety; correct?

A. That's correct.

Q. Let's turn to Page 4. And this is in the section that talks about obligations of McKesson. And this is language I think you were shown yesterday.

If we go to (e), "McKesson agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders is hereby rescinded and is of no legal effect."

Do you see that language?

A. Yes.

Q. Am I correct that you saw a need to write into this agreement that any prior approvals, express or implied, by DEA were rescinded?

A. Yes. We put that in there because, again, the industry as a whole felt there were approved systems and we wanted to make sure that was correct.

Q. And we talked about how you came into Diversion Control

in 2005; correct?

A. That's correct.

Q. Just "yes" or "no" have you seen documents that led defendants, including McKesson, to believe that their systems had been approved prior to that time?

A. No, I don't believe I have seen a document.

Q. Okay. Let's go on to Page 6, please. And you were shown -- well, let's start with (e). Do you see that it says, "Within 150 days of the effective date of this agreement, but not earlier than 90 days after the effective date of this agreement, DEA shall conduct reviews of the functionality of McKesson's diversion compliance program at up to eight distribution centers of McKesson."

Do you see that language?

A. Yes.

Q. And you understand that when this is talking about conducting reviews of the functionality of McKesson's diversion compliance program, it's talking about that CSMP that we referred to before the break?

A. Whatever system was in place at that time.

Q. And do you take issue with the CSM -- with the testimony the Court has heard about the CSMP being in place at that time?

A. No, I don't take issue with it. I'm just saying whatever system we had in place at that time.

Q. Got it. And you would -- if we look at this section, this section appears in a portion of the report if you want to look back at Page 5.

Let's put it up on the screen for just a second.

This appears in the section of the report talking about the obligations of the DEA. Do you see that?

A. Yes.

Q. So let's go back to Page 6. Would you expect the DEA to meet their obligation to conduct reviews of the functionality of McKesson's diversion compliance program?

A. Yes.

Q. All right. The next sentence says, "DEA shall also review the investigatory files maintained by McKesson of the customers serviced by the distribution centers subject to the compliance reviews."

And let's just underline "review the investigatory files" if we could at the end of the second highlighted line from the bottom where it says "review the investigatory files."

Would you expect the DEA to meet their obligation to review the investigatory files maintained by McKesson of the customers serviced by the distribution centers subject to the reviews?

A. Yes.

Q. It goes on. Let's skip a sentence. It says, "During

the course of the compliance review, if requested McKesson shall provide DEA with information related to the sales of controlled substances, non-controlled drugs, and listed chemicals from the effective date of the agreement to the date of the compliance review by the particular distribution center being reviewed."

Did I read that correctly?

A. Yes.

Q. Would you expect the DEA to ask where they thought it was appropriate for -- and let's underline "sales of controlled substances, non-controlled drugs, and listed chemicals."

A. Yes.

Q. And then it says at the conclusion of each compliance review, DEA shall conduct an exit interview with an appropriate McKesson representative to provide DEA's preliminary conclusions regarding the compliance review.

Do you see that reference to the exit interview?

A. Yes, I do.

Q. Do you know -- would you expect those exit interviews to have occurred given this obligation in this Settlement Agreement?

A. Yes.

Q. Do you know of any concerns raised in those exit interviews with McKesson on any of these points, the

functionality of its diversion compliance program, the investigatory files maintained, or any information requested in these other categories?

A. No, I do not know personally.

Q. Let's look at Subsection (f), please. That's the next section in the 2008 Settlement Agreement, Page 6 of Defense West Virginia -- I'm sorry -- P-23733.

You were shown this sentence at the end that says, "A finding of satisfactory does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center."

Do you remember being shown that language yesterday?

A. Yes.

Q. Do you see where it says "does not otherwise express approval"?

A. Yes.

Q. So let's look at what is being reviewed.

The first sentence says, "The compliance reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has, one, failed to maintain effective controls against diversion regarding the distribution of any controlled substance."

Do you see that?

A. Yes.

Q. "Two, failed to detect and report to DEA suspicious

orders of controlled substances."

Do you see that?

A. Yes.

Q. Or, "Three, failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances."

Do you see that?

A. Yes.

Q. Would you expect the DEA to carry out its responsibilities to only deem these compliance reviews satisfactory unless there's a finding of failure to maintain effective controls, failure to detect and report suspicious orders, or failure to meaningfully investigate new or existing customers?

A. Yes, during that, during that snapshot period of review, yes.

Q. And you know McKesson passed those compliance reviews; correct?

A. Yes, during that snapshot period of review, yes.

Q. And you know of no concerns that the DEA raised on any of these specific factors that they were reviewing in order to deem the distribution center satisfactory?

A. Again, during that, that short time period of review, yes, they did not find anything.

Q. I want to come back to a point we talked about before

the break. Did I hear you correctly that although it doesn't appear in the regulation, you said in your distributor letters that they were supposed to identify for a suspicious order what the issue is with the pharmacy? Did I understand that correctly? Remember I said I'll come back to that?

A. Yeah. I -- they were supposed to explain what created the suspicious nature of the order which is basically due diligence.

Q. Were they -- sorry.

A. A suspicious order is not just, oh, it's over the threshold. It could be over threshold because it's next to a cancer center or palliative care center, a hospital. There's got to be something just -- threshold, that's exactly what due diligence is. It's looking at a suspicious order above threshold. There's got to be some reason it's above threshold. And that's got to be explained, yes.

Q. Did you testify before the break that you told distributors in your letters that they had to identify what the issue with the pharmacy was when they reported a suspicious order to that pharmacy? Did you give that testimony?

A. Yes, I believe I said the letters and/or -- I think it was the letters or the distributor initiative briefings, but I think I said letters, yes.

Q. I think you did too. So let's take a look at those letters. Do you have in front of you P-32, sir? This is the packet that contains the letters.

A. Yes.

Q. Okay. And go to Page 9. Do you see your September 27th, 2006, letter?

A. I don't think it's in the 2006 letter.

Q. Okay. If you don't think it's there, let's go to the December one. If you go to Page 3, do you see your December 27th, 2007, letter?

A. Yes.

Q. Let's go to the second page, please, and if we can cull out the second paragraph.

It states, "When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious."

Do you see that?

A. Yes.

Q. That's that idea you have to tell us you think it's suspicious under your criteria; correct?

A. Yes.

Q. Is there anywhere in this letter where you tell them you have to explain what it is about the pharmacy that makes it suspicious?

A. That's due diligence. So, naturally, just over threshold tells us nothing. It needs to be more than that. No, in that letter, no, there's nothing. But we've explained to them -- we explained to them in the distributor initiative briefings what due diligence is.

Q. I'm not asking about due diligence, sir. I'm asking about reporting suspicious orders. You did not attend the due diligence briefings with McKesson, ABDC, or Cardinal; correct?

A. That's correct.

Q. And in your letter, your letters, you do not tell McKesson, ABDC, or Cardinal that they need to, when they report suspicious orders, explain what it is about the pharmacy that is triggering the report; correct?

A. Well, a suspicious order is specific on the pharmacy. So it's not in that letter. However, --

Q. It's not in any of your letters, is it, sir?

A. No. Now that I -- I know it's not in the '6 one so --

Q. Okay. Let's, let's switch gears. I want to talk about the closed system. Do you remember giving testimony that was one of the stops, or several of the stops on the road map, the closed system?

A. Yes.

Q. Let's go back to those stops on the road map. And I want to start with the mission of the Office of Diversion

Control. And I'll give you a document I've marked as Defense West Virginia 2408.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

THE WITNESS: Thank you.

MR. SCHMIDT: Thank you.

BY MR. SCHMIDT:

Q. Do you have that in front of you, Defense West Virginia 2408?

A. Yes.

Q. Do you recognize it as a printout from the Diversion Control division at DEA that talks about their mission?

A. Yes.

MR. SCHMIDT: We move this into evidence, Your Honor.

THE COURT: Any objection?

MR. ACKERMAN: The objection is foundation, Your Honor. I don't know that -- it talks about the -- it's not related to a time period where he was at DEA.

BY MR. SCHMIDT:

Q. Do you recognize this --

MR. SCHMIDT: I'll take care of that, Your Honor, if I could.

BY MR. SCHMIDT:

Q. Look with me under "About Us." Do you see that?

A. Yes.

Q. Just read to yourself the mission of DEA. Do you see that? Tell me when you've had a chance to read that.

(Pause)

A. Yes.

Q. Do you recognize that as the mission of the Office of Diversion Control when you were at DEA?

A. Yes. That's a mission statement we used.

MR. SCHMIDT: I move it into evidence on that basis, Your Honor.

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. So I want to break down that mission a little bit and I want to start -- well, let me ask, do you recognize this? It's a two-part mission, correct, according to this mission statement?

A. Yes.

Q. I want to talk about both parts of that mission if I could. Let me see if I can switch to the white board if that's okay.

Do you still have that language in front of you, Mr. Rannazzisi? I'm just going to write part of it up on the screen if that's okay.

MR. SCHMIDT: Am I okay erasing this?

MS. SINGER: I think it's been saved. Excuse me. I think it's been saved.

MR. SCHMIDT: Okay.

MR. ACKERMAN: Your Honor, I'm going to move over there so I can see the board.

THE COURT: You may.

BY MR. SCHMIDT:

Q. All right. So looking with me at Exhibit 2408, is part of the mission of the Office of Diversion Control to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals? Is that one of the missions of Office of Diversion Control?

A. Yes, it is.

Q. I'm going to shorthand it by writing "prevent diversion." And then it continues on and says, "while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."

Do you recognize that as the other mission of the Office of Diversion Control?

A. Yes.

Q. Let me -- "while ensuring an adequate and uninterrupted supply." And let me ask you about both halves of this starting with preventing diversion.

In preventing diversion and in carrying out that mission, the DEA is charged with protecting the public from

the harms of diversion; correct?

A. That is correct.

Q. In fact, one of the DEA's core functions is to prevent the diversion of controlled substances into illicit channels; correct? That's a core function of the DEA?

A. Yes.

Q. At the same time, and I think you talked about this in some of your testimony yesterday particularly on quota, DEA has a mission to ensure an adequate and uninterrupted supply of controlled substances; correct?

A. That's correct.

Q. And you agree that it's vital that an adequate and uninterrupted supply of pharmaceutical controlled substances be available for effective patient care?

A. Yes.

Q. It's a public health concern when pharmacies cannot dispense legitimate pharmaceutical controlled substances to patients; correct?

A. To legitimate patients, yes.

Q. There can be no doubt that drug shortages adversely affect the public health; correct?

A. That's, that's obvious, yes.

Q. All right. From your experience, you agree that when it comes to the supply of prescription opioids, supply does not drive demand?

A. Supply does not drive demand.

MR. ACKERMAN: Your Honor, while Mr. Schmidt is writing, if it's at all possible for the Court to move that to our screens, then I don't need to stand here with my friends.

MR. SCHMIDT: Yeah, no objection, of course.

THE COURT: Yeah. Just find a good place there, Mr. Ackerman.

MR. SCHMIDT: I'm sorry. Before you switch it, the problem is that we may need to put up documents on the individual screen.

MR. ACKERMAN: All right. I'll find a chair over here.

MR. SCHMIDT: There's an empty one at my table.

(Laughter)

BY MR. SCHMIDT:

Q. Going back to this point, when it comes to demand for prescription opioids, that comes not from supply but from prescribing and dispensing in hospitals; correct?

A. No, not necessarily. Demand also -- when we're talking about quota, it has things to do with research and development, validation, export, things like that.

Q. When it comes to -- let me rephrase. When it comes to demand, demand comes from things like prescribing, hospitals, research and development, export; correct?

A. For that portion of the quota. Well, yeah, total, yes.

Q. The demand is driven by patient care and patient needs; correct?

A. A large part of the quota is patient needs.

Q. Not by supply; correct? I didn't hear if you answered. I apologize, sir. Not by supply; correct?

A. No, supply is not what drives demand.

COURT REPORTER: I'm sorry?

THE WITNESS: Demand drives the quota.

BY MR. SCHMIDT:

Q. Your understanding of what drives demand for opioids is appropriate medical treatment; correct?

A. Yes, if -- appropriate medical treatment, yes.

Q. And prescription opioid levels in turn -- prescription opioid levels in turn are based on the presumption that medical need is legitimate; correct?

A. Yes. Appropriate medical treatment does drive some of the demand, yes.

Q. And just because you have a supply of prescription opioids does not mean the supply must be used; correct?

A. That's correct.

Q. Correspondingly, reducing supply doesn't necessarily reduce demand; correct?

A. That's correct.

Q. All right. Now, in terms of supply level, you never

provided guidance at DEA to tell companies that for a given dose or type of prescription opioid if they see doses above that level, they should investigate, did you?

A. I personally didn't.

Q. Okay.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've passed you a document marked P-23594-001. Do you know what this document is?

A. Yes. I believe these are the summary reports that we put on the DEA website.

MR. SCHMIDT: I move this into evidence, Your Honor.

THE COURT: Yes.

MR. ACKERMAN: No objection.

THE COURT: Did you move its admission?

MR. SCHMIDT: I did, Your Honor.

THE COURT: And there's no objection; right?

MR. ACKERMAN: No objection.

THE COURT: I was reading it and I wasn't paying attention. It's admitted.

BY MR. SCHMIDT:

Q. All right. If we look at the cover of this document, do you see it says "Department of Justice"?

And it's on your screen as well, just not on the big screen.

A. Yes.

Q. And it says "ARCOS Report 4." Do you see that?

A. Yes.

Q. And it says reporting period January, 2010 to December, 2010. Do you see that?

A. Yes.

Q. And this is, this is that portion of the ARCOS data the DEA reported to the public; correct?

A. Yes.

Q. And I've chosen this period of time because there's been a focus on this period of time in terms of a high level, or purportedly high level of prescription opioids during this time period.

So let's -- having said that, let's look at Page 21 of this report. Actually, let's start with Page 18. I apologize.

And if we look at -- tell me when you're there, sir.

A. I believe I'm there.

Q. Okay. If you look at the left-hand side about two-thirds of the way down, and if you can pull it up a tiny bit, just pull up the screen a tiny bit. There we go.

It says U.S. grams per hundred thousand, Drug Code 9143, drug name hydrocodone [sic].

Do you see that?

A. Yes.

Q. Do you have an understanding that this is the DEA reporting the average grams per hundred thousand people for different states for oxycodone?

A. Based on ARCOS, yes.

Q. Correct?

A. It's the amount of drugs that ARCOS, on an ARCOS analysis has gone into these states per 100,000.

Q. And if we look at West Virginia, West Virginia is 9. Do you see that?

A. Yes.

Q. Let's go to 21. And, very quickly, do you see that 21 reports the same data for hydrocodone? This time West Virginia at this point in time is number 7. Do you see that?

A. Yes.

Q. When you were at DEA, did you ever issue guidance to distributors, the healthcare community, doctors that these levels were too high?

A. No, I did not.

Q. Are you aware that the DEA also publishes this data at the zip code level?

A. I'm sorry?

Q. At the zip code level.

A. Yes, uh-huh.

MR. SCHMIDT: May I approach?

THE COURT: Yes. You should have bought stock in International Paper, Mr. Schmidt.

MR. ACKERMAN: At some point, Your Honor, I'm sure someone is going to object on behalf of the earth.

MR. SCHMIDT: Someone should. I'm happy to do less.

BY MR. SCHMIDT:

Q. This is a lot of paper for a little point.

Do you see that this is 23591 and it's a similar retail drug summary report, but this time by zip code within the state? Do you see that?

A. Yes.

MR. SCHMIDT: We move this into evidence, Your Honor.

THE COURT: Any objection?

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. Let's look at Page 354, please. Do you see that on Page 354 -- I thought it said oxycodone on this page. I'll represent to you that this is the oxycodone levels. You can flip back in the report to confirm that.

Do you see the report of the oxycodone levels by zip

code on Page 354?

A. Yes.

Q. And if we look at zip codes 255 and 257, do you see those zip codes?

A. Yes.

Q. And I'll represent to you that those zip codes include Huntington and Cabell County, but they also include additional areas. Is that something you were aware of?

A. No.

Q. Did DEA ever issue any guidance in connection with issuing a report like this at any point in time to healthcare providers, manufacturers, distributors, pharmacies that specific levels at the zip code level were too high?

A. No. DEA would not issue something like that.

Q. Did they ever say certain levels merited investigation?

A. No. The reason this is put on there is to help healthcare providers, public health officials, law enforcement, different organizations knowing what's going into their systems. That's why it's on the DEA website.

Q. That was the intent, to let entities like the City of Huntington and Cabell County know exactly what was going into their communities?

A. Health departments, state health departments, things like that. We wanted to get it out there about exactly

population wise how much drug is going into the areas.

Q. So that they could act as appropriate if they deemed it appropriate?

A. The information was presented for their -- whatever they deemed appropriate.

Q. Okay. I want to talk about some of the participants now in the closed system that you touched on with the Court yesterday and the day before.

Anyone who handles a controlled substance has to be registered with the DEA; correct?

A. Except for nurses and pharmacists.

Q. Nurses have to operate under the direction of doctors; correct?

A. Or hospitals.

Q. Or hospitals. And pharmacists have to be affiliated with a pharmacy that's registered; is that correct?

A. Yes, uh-huh.

Q. And that DEA registration includes prescribers; right?

A. Yes.

Q. Prescribers can only write prescriptions for prescription opioids if they're licensed with their state but also if they're registered with the DEA; correct?

A. Yes.

Q. Did you have an understanding when you were at the DEA as to why there's a separate requirement for DEA

registration in addition to the requirement that they be licensed by the state?

A. So a DEA registration authorizes them to have a -- to handle controlled substances. The state registration, because they're licensed to practice medicine or whatever they're practicing, and also there's a separate state license for controlled substances but -- in some states.

So there's -- it's a two-part system. You've got to be registered by the state. The state has to grant you a license. And then DEA will come and grant you their license.

Q. My question was a little different, sir. My question was why is there a DEA requirement of a separate DEA registration in order to prescribe controlled substances, if you know? Why not just have the state requirement?

A. Because under the Controlled Substances Act it's required.

Q. Do you know why?

A. Yeah, because the federal government wants to ensure that controlled substances under the Act are being handled appropriately.

Q. You understand that registration had to be renewed every three years?

A. Yes.

Q. And just so -- actually, I'll skip moving in the

regulation.

Did you have an understanding when you were at DEA as to why prescribers weren't simply given a lifetime registration from DEA, why they had to be renewed every three years?

A. To ensure that they're appropriately licensed and that they did not have anything in their backgrounds during that three-year period that could warrant them, you know, disqualifying them from getting a license, a DEA registration.

Q. I'm going to show you P-4215 if I could. I just misread it. I apologize. It's P-42145.

MR. SCHMIDT: May I approach, Your Honor?

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, do you recognize this as a DEA regulation regarding prescriptions for controlled substances?

A. Yes.

MR. SCHMIDT: We move this into evidence, Your Honor.

THE COURT: Any objection?

MR. SCHMIDT: P, Plaintiffs' 42145.

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. In this regulation in the second sentence it states, "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner."

Do you see that language?

A. Yes.

Q. And then it refers to a corresponding responsibility with the pharmacist who fills the prescription; correct?

A. That's correct.

Q. And only a DEA registered practitioner may make the determination if a controlled substance is medically necessary; correct?

A. For a particular patient.

Q. Yes.

A. For prescribing, yes.

Q. And a distributor cannot make the determination if a controlled substance is medically necessary for a particular patient; correct?

A. Yes. And we've never asked a distributor to do that.

Q. Fair. In fact, yesterday you testified that you were not asking distributors to become doctors and figure out what's legitimate and what's not; correct?

A. That's correct.

Q. Yesterday you testified that you never required distributors to look at what doctors were doing, questioning

a doctor's prescribing habits; correct?

A. That's correct.

Q. Why are DEA registered practitioners the only ones who can make the determination that a medication is appropriate for an individual patient?

A. Because they have to make a determination that the medication that they're prescribing meets the needs, medical needs of that particular patient. They're seeing that patient. No one else is.

Q. Okay. Was there ever an occasion you know of where you or someone at DEA told one of the distributors in this case that they should stop supplying to a pharmacy in Huntington or Cabell because of a DEA registered doctor whose prescriptions were being filled at that pharmacy?

A. I've never done that, and I don't know of anybody among the staff that has when I was there.

Q. You would agree with me that -- and I think you talked about some of these statistics yesterday. I just want to make sure we're on the same page.

During your time at DEA, 99.5 percent of prescribers were not over-prescribing; correct?

A. Yeah, we used that number. We generally used 99 percent but we've gone to .5.

Q. And I don't want to quibble, but because I've written 99.5 on the board, do you want to see your congressional

testimony where you said that?

A. That's fine.

Q. You don't take issue with it; right?

A. We've used 99 percent too. It just depends on when we're talking.

Q. Yeah, understood. And that's what I want to go to next. You've actually said 99 percent of doctors are perfect. Correct?

A. Yeah, I've said that they're doing things appropriately, yes.

Q. That they're perfect; correct?

A. I don't recall saying "perfect," but I may have during one presentation.

MS. SINGER: Objection, Your Honor. I don't think what Mr. Schmidt wrote is what Mr. Rannazzisi just testified.

MR. SCHMIDT: Let me see if I can cure that, Your Honor.

BY MR. SCHMIDT:

Q. Defense West Virginia 620. Do you remember being asked about giving congressional testimony at various points in time, Mr. Rannazzisi?

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

THE WITNESS: Yes.

MR. SCHMIDT: If there's no objection, we'll start doing excerpts on these bigger documents. It does seem a waste to do all this for a small part at this point.

BY MR. SCHMIDT:

Q. If we look at Defense West Virginia 620, it's a hearing before a House of Representatives Committee, March 1st, 2012. Do you see that?

A. Yes.

Q. And then if we go to -- I'm using the numbers in the lower left corner, Page 98. You'll see various comments from you, including a larger one in the top half, right barely above the top half of the page. Do you see that?

A. On page -- which page?

Q. Page 98 in the lower left-hand corner.

A. Yes, I've got it.

Q. And if you look at the second sentence there that begins "the problem," do you see that? Do you see where you say, "The problem is that the doctors continue," and then you stop, "not all doctors, 99 percent of the doctors are perfect."

Do you see that you said that before Congress?

A. Maybe I'm not on the right page then. What's the page on top?

Q. The page on top is 94.

A. Okay. I'm there.

Q. And it's the third quote from you on the page right before the halfway mark.

A. Okay. I see it. I see it.

Q. Do you see where you said to Congress 99 percent of the doctors are perfect? Do you see that?

A. Yes.

Q. Were you trying to be accurate and correct in your testimony to Congress?

A. I was giving an estimate on what DEA has said in the past.

Q. Okay.

THE COURT: Do you still object, Ms. Singer?

MS. SINGER: I don't think it's worth the objection, Your Honor, so I withdraw the objection.

MR. SCHMIDT: Thank you.

BY MR. SCHMIDT:

Q. You repeatedly stated, including to Congress throughout your tenure, that the overwhelming majority of prescribing in America is conducted responsibly. Correct?

A. Yes.

Q. And during your tenure, you also said that the DEA recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the usual course of professional practice;

correct?

A. Where, where did I say that? I've got to go back and look at that.

Q. Okay. Let's take a look at that.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. This is a statement from the Federal Register DEA -- while you were at DEA. Do you see that? September 6th, 2006?

A. Yes.

Q. Okay.

MR. SCHMIDT: We move this into evidence, Your Honor, Defense West Virginia 3076.

THE COURT: Any objection to this one?

MR. SCHMIDT: Actually, this is in evidence. Nevermind.

THE COURT: Oh, it's in evidence.

MR. SCHMIDT: I'm sorry.

BY MR. SCHMIDT:

Q. Let's go to the second page.

A. Uh-huh.

Q. On the second page in the upper left corner it says, "Drug Enforcement Administration." And it says "Action: Policy Statement." Do you see that this is a policy

statement of the DEA while you were there?
A. Yes, sir. I was -- yes, sir.
Q. It's a policy statement regarding, quote, dispensing controlled substances for the treatment of pain. Do you see that?
A. Yes.
Q. And it's a policy statement, if we look for further information -- if we look -- strike that. If we look a little further down, it says, "For further information, contact." Do you see that?
A. Yes.
Q. And it has someone in the Office of Diversion Control, the office you oversaw. Do you see that?
A. Yes.
Q. And did you supervise this person, Mr. Caverly?
A. Yes.
Q. Were you responsible for this policy statement when it came out?
A. We were a part of drafting of this policy statement, yes.
Q. Okay. So let's look at this policy statement. This is one of those documents that we talked about yesterday with Ms. Singer that were issued to give guidance to doctors and others. Right?
A. I've got to re-read this policy statement. I -- it's a

policy statement regarding the treatment of pain, if I'm not mistaken.

Q. Okay.

A. But I have to go back and read it. If this is the same one I'm thinking about, it's very detailed and there's a lot of information. So I would have to go back and read this. But --

Q. Okay.

A. So let me just -- with that caveat.

Q. Okay. Let me see if I can help you. Let's go to the second page on the right-hand column. And it says -- you've got it on the screen.

It says "Purposes and structure of this document." Do you see that?

A. Yes.

Q. And this document came from the Office of Diversion Control; correct?

A. It -- well, it came from the administrator. The administrator signed the document.

Q. You had a role in this document; correct?

A. I was at the Office of Diversion Control during this time period.

Q. Did you have a role in this document?

A. I, I reviewed the document, yes.

Q. One of the chief purposes of the document is to make

clear that the long-standing requirement under the law that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment.

Do you see that?

A. Yes.

Q. This was giving guidance to doctors; right?

A. Yes.

Q. All right. And then if we go to Page 7, please, in the lower left corner, and tell me when you're there.

A. Okay.

Q. And I'm going to direct your attention to the right-hand column right before the bolded heading which we have up on the screen. And it has that language I started off by reading.

"To the contrary, the agency recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the usual course of professional practice."

Was that stated in the policy statement from the DEA when you were at the DEA running the Office of Diversion Control?

A. Yeah. I don't remember that statement but, again, I

know this document was not just -- it was published as a DEA document, but there were other, other agencies and government agencies and entities involved in this document.

Q. Okay. But you see where it says nearly every prescription -- and I'm going to write Rx for short -- is for a legitimate medical purpose. Do you see that?

A. Yes.

Q. Do you take issue with this as a true statement, sir?

A. From -- I would say, I would say the vast majority of the prescriptions. I wouldn't say nearly every. Nearly every is pretty, pretty focused. I don't think that's the case.

Q. Did you ever take any steps to repudiate this statement in an official DEA policy statement on your watch?

A. Again, it's official policy statement that was made by not only DEA but the department and other entities within the United States government. It just was a vehicle. The DEA Federal Register was the vehicle to get that out.

Q. Do you mind answering my question now, sir?

A. Which is?

Q. Did you take any steps to repudiate that statement while you were at DEA?

A. I don't recall taking any steps to retract or repudiate the statement.

Q. Okay. In the same document you talked about the idea

of doctors acting improperly, and I want to direct your attention to that.

Could we go to Page 5 of this document. And tell me when you're there.

Let's cull up the right-hand column, just the heading.

A. Okay. I'm on Page 5.

Q. Can we cull up Page 5, Defense West Virginia 3076, so we're all looking at the same thing. Is it available to put up on the screen? Thank you.

And while we do, let me read the title in the record, the heading -- I'm sorry -- of this subsection.

It says, "The number of physicians who prescribe controlled substances in violation of the CSA --" and now we see it on the screen -- "is extremely small and there is no DEA crackdown on physicians."

Do you see that in this policy statement that when it comes to the physicians who prescribe controlled substances in violation of the CSA, that is extremely small? Do you see that?

A. Yes, as compared to the patient population, yes, the physician population, prescriber population, yes.

Q. That's a true statement; right?

A. Yes.

Q. And it then goes on to characterize that. It has that "overwhelming majority" language you and I have talked

about. DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes.

Do you see that?

A. Yes.

Q. In fact, the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by federal or state law enforcement officials. Do you see that?

A. Yes.

Q. And is that a true statement?

A. Yes.

Q. And then you quantify actions against doctors in the italicized sentence, if we can scroll down in this column, please.

Do you see a little further down there's an italicized sentence? Do you see that?

A. Yes.

Q. "In any given year, including 2005, fewer than one out of every 10,000 physicians in the United States (less than .01 percent) lose their controlled substance registrations based on a DEA investigation of improper prescribing."

Did I read that correctly?

A. Yes.

Q. Is that accurate that in a given year less than

.01 percent of physicians in the United States lose their controlled substance registration based on a DEA investigation of improper prescribing?

A. Back in 2005 and prior to, yes.

Q. Was that true in 2007 when you gave the same testimony before Congress?

A. I'm not sure in 2007 if that's true or not. I would, I would guess that the numbers -- I just don't recall. But, but this is specific to prior to 2005. So if there's some other document or -- I've looked at it, but I just don't recall saying that except for 99 percent of the prescribers. Generally, 99 percent of the prescribers are doing exactly what they're told to do.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: Actually, can we just put it up on the screen because it's impeachment? We have it here.

THE WITNESS: Thank you.

MR. SCHMIDT: You're welcome.

BY MR. SCHMIDT:

Q. I've passed you MC-WV-2172, testimony before House of Representatives Subcommittee on July 12th, 2007. Do you see that?

A. Yes.

Q. If you go to Page 11 in the bottom left-hand corner

you'll see a prepared statement from you read into the record. Do you see that?

A. Yes.

Q. And if you go to Page 12, the fifth full paragraph, generally speaking, do you see you again in July of 2007 saying, "In any given year DEA arrests less than .01 percent of the 750,000 doctors registered with the DEA for a criminal violation." Do you see that?

A. Yes. That's specific to a criminal violation.

Q. Okay.

A. That's what it says, a criminal violation.

Q. Okay.

A. It doesn't say anything about administrative actions.

Q. I'm not going to ask you about those further. Do you want me to take back any of those large documents?

A. I would love for you to take back some of these large document.

Q. That's the only time you'll ever say that to me. But the testimony, if you want to give me that, all the suspicious order reports, if you want to give me those.

A. Yes.

Q. All right. So if we go back to this 2006 policy statement from DEA, Defendants' West Virginia 3076, I want to go back to Page 5, please. And let's look at that italicized sentence we were highlighting.

Have you ever publicly identified what percentage of opioid prescriptions in a given year are written by this .01 percent versus the remaining 99.9 percent? Is that something you've ever quantified for the public?

A. No.

Q. Do you know if any of the doctors in Huntington or Cabell on your watch were in this .01 percent?

A. I do not know.

Q. And when you identified those .01 percent who lost their registrations on the other example were criminally prosecuted, did you make that determination just by looking at their prescribing levels or did you require more information?

A. Oh, it would require an investigation, a full investigation.

Q. Did you ever have a criteria that if a doctor fell within the top one percent, they would automatically be investigated in terms of their prescribing levels?

A. Doctors are investigated based on a specific set of facts. And after that, you know, we get into an investigative process.

Q. My question was simply was there ever --

A. I'm sorry. I said doctors investigated by specific -- it's fact-based, specific set of facts. So we don't investigate based on quantities.

Q. You answered my question. Thank you. You looked at a range of factors to determine --

A. A range of factors, yes.

Q. A range of factors beyond simply quantity; correct?

A. Yes, for doctors, yes.

Q. Yes. Now, the DEA made these statements about prosecutions being rare in the context of wanting to encourage doctors that they could prescribe prescription opioids as medically appropriate without being concerned about the DEA cracking down on them; correct?

A. We wanted to assure doctors that if they were prescribing appropriately, they would never have problems with DEA as long as they were prescribing for legitimate medical purpose in the usual course of professional practice.

Q. In fact, if we look at -- if we look at the document we were just looking at 3076-5, the policy statement, the language we were just looking at, the heading, Page 5, that heading says there is no DEA crackdown on physicians; correct?

A. I don't know where -- this is not --

Q. It's Page 5 on the right-hand side, the boldfaced heading.

A. Page 5, right-hand side.

Q. There is no crackdown -- no DEA crackdown on

physicians. That's what you were reassuring doctors of; correct?

A. Yes.

Q. And you've said in your testimony before Congress that doctors should not hesitate and should continue to provide patients with whatever treatment they feel appropriate as long as it's for a legitimate medical purpose and done in the usual course of medical practice; correct?

A. That's the standard, yes.

Q. And let's go to Page 6 in this document, Defense West Virginia 3076. In the upper left-hand corner it states, "It would be a disservice to many patients if exaggerated statements regarding the likelihood of a DEA investigation resulted in physicians mistakenly concluding that they must scale back their patient's use of controlled substances to levels below that which is medically appropriate."

That's a true statement; correct?

A. Back in 2006, yes.

Q. And just to be clear, there was an opioid crisis in 2006; correct?

A. There was, yes.

Q. Now, you gave specific guidance in this document; correct?

A. I'm, I'm not sure where -- if you point it to me, I'm more than happy to read it.

Q. Sure. Let's go to Page 9, please, Defense West Virginia 3076. If we could blow up the top in the middle column, please.

Do you see in the top of the middle column, if you want to read to yourself the language that precedes that in the prior column. I'm going to focus on the second line.

Do you see that it says, "Courts have recognized that prescribing an inordinately large quantity of controlled substance can be evidence of a violation of the CSA."

Do you see that?

A. Yes.

Q. And that's this idea about having exceptionally high levels; correct?

A. Yes.

Q. And then I want to read what you write below that if we can scroll down in this paragraph.

The next paragraph begins, "Nonetheless, the amount of dosage units per prescription will never be a basis for investigation for the overwhelming majority of physicians."

Do you see that?

A. Yes.

Q. That's a true statement; correct?

A. Back in 2006, that was a very true statement.

Q. Was this statement in this DEA policy statement in 2006 ever repudiated on your watch?

A. Well, remember, as I said before, this is not a -- this is not just a DEA state policy statement. There were other agencies involved in this including the Department of Justice. DEA was the vehicle to get that out. If you notice, I did not sign the policy statement. It was signed by the administrator of the Drug Enforcement Administration.

Q. Do you know if DEA --

A. That was a statement.

Q. Do you know if it's ever been repudiated by DEA?

A. I never repudiated it. I have no idea if it was ever repudiated after I left.

Q. Okay. Fair enough. Let's scroll down in this paragraph. After saying that the amount will never be the basis for investigation for the overwhelming majority of physicians, if we go a sentence down, it states, "In rare cases, it is possible that an aberrant physician could prescribe such an enormous quantity of controlled substances to a given patient that this alone will be a valid basis for investigation."

Do you see that statement?

A. Yes.

Q. That was true when it was made; correct?

A. It was, it was -- if it's in this document, it was true at the time.

Q. Okay. And then it gives an example. And before

looking at the example, let's scroll down to see what it says after the example.

Could we look at the sentence beginning "again" a few lines down? If you take that down and go to the middle column, please. And probably 10 lines from the bottom, four words in it begins "again, however," just above where your cursor is in the middle column. "Again, however, such cases are extremely rare." Can you cull that out?

Do you see where after giving this example of when levels might be excessive it says, "Again, however, such cases are extremely rare." Do you see that?

A. Yes.

Q. It continues, "The overwhelming majority of physicians who conclude that use of a particular controlled substance is medically appropriate for a given patient should prescribe the amount of that controlled substance which is consistent with their sound medical judgment and accepted medical standards without concern that doing so will subject them to DEA scrutiny."

Do you see that?

A. Yes.

Q. Okay. So when we were looking at this language, we skipped over the example that was given. I want to go back now to that example that was just above that.

And, so, this is an example of when, in the words of

the preceding sentence, there is such an enormous quantity of controlled substances to a given patient that this alone will be a valid basis for investigation, for example.

Do you see that language?

A. Yes.

Q. And the example provided of when there might be -- in this 2006 DEA policy document of when there might be such an enormous quantity of controlled substances to a given patient that this alone will be a valid basis for investigation is if a physician were to prescribe 1,600 tablets, and let's underline "1,600," per day, underline "per day," of a Schedule II opioid to a -- and let's underline "single patient." Do you see that?

A. Yes.

Q. And am I correct that this is the only example provided in this DEA policy document to doctors and the healthcare community of what constitutes such an enormous quantity of controlled substances to a given patient that this alone will be a valid basis for investigation? I don't see any other examples. Do you?

A. I, I don't know. I'd have to go through.

Q. If you need to look, take a look. I'm representing that there are none.

A. Okay. Well, I trust you. Well, --

(Laughter)

MR. ACKERMAN: Move to strike, Your Honor.

MR. SCHMIDT: I think he struck it himself, a moment of candor taken back.

THE WITNESS: No, there's other, there's other examples in here. I have to read the examples, but there are other examples.

BY MR. SCHMIDT:

Q. Show me the examples that -- and I'm focused on something specific.

A. I know. But I don't know until I read the examples. You have the Smith example, the Bischoff example, the Poulter example, looks like Singh. So there's other, there's other examples here.

Q. Okay. And that's why I tried to tailor my question, sir.

A. Okay.

Q. See where it talks about in rare cases it is possible that an aberrant physician could prescribe such an enormous quantity of controlled substances to a given patient that this alone will be a valid basis for investigation? Do you see that?

A. No, I understand that. But I think to, to, to -- without looking at these other cases, I don't know what the quantities were in these cases and I don't know what the cases -- the foundation of the cases were. So if I agree to

that, I mean, I don't think that would be doing the Court justice.

Q. Fair enough. Let's stick to the example we see here on the page where it says "for example" right before saying, "Again, such cases are extremely rare."

A. Okay.

Q. 1,600 per day for a single patient. Do you see that?

A. Yes.

Q. Do you know why DEA in this policy statement that you had a part in didn't say if a physician were to prescribe 100 tablets per day of a single opioid to a single patient, that would certainly warrant investigation?

A. Again, I'm not sure why this was in there.

Q. Okay.

A. But I can tell you the Office of Diversion Control doesn't necessarily go by quantity, but they always investigate pursuant to legitimate medical -- prescribing for a legitimate medical purpose in the usual course of professional practice.

And while quantity is not an issue, we do look at other factors that would open that investigation, and quantity would be part of that once the investigation is opened.

Q. Do you know why the DEA didn't say 1,000 pills a day for a single patient would certainly warrant investigation?

A. I don't know. But it looks like they were just looking

at trying to explain some egregious quantity. I don't know what the thought process was of the person that wrote this section.

Q. You agree with me that -- and I can give you a calculator if you want. If you multiply 1,600 by 365 days, by my math you get about 584,000 pills from a single doctor to a single patient in this example.

A. Well, I trust your math.

Q. Let me just check it myself just to be sure. 584 -- I'm sorry. Let me do again because I might have gotten it wrong. 584,000.

Did you ever tell doctors -- let's take a smaller number -- that if they wrote half a million pills to a single patient in a single year that in the words of this guidance, that would certainly warrant an investigation as there is no conceivable medical basis for anyone to ingest that quantity of such a powerful narcotic? Did you ever give that guidance, that half a million instead of 584,000?

A. I'm sorry. You're going to have to repeat that.

Q. Sure. At DEA are you aware of DEA ever giving doctors -- we're talking about 584,000 pills a year here; correct?

A. Okay.

Q. Did you ever give guidance to doctors that a lesser amount, half a million pills in a year, would certainly

warrant investigation?

A. No, we didn't give guidance. But, obviously, 1,600 pills a day is almost an impossible quantity for opioids. It is an impossible quantity. It's a ludicrous quantity.

So I think what they were doing was saying here's an example and just throwing up a number that is so unrealistic that no one would ever meet that.

Q. So other than giving an example that is impossible, ludicrous, and so unrealistic as what would certainly warrant investigation, is there any realistic possible non-ludicrous number that the DEA gave doctors that in the words of this policy statement from 2006 would certainly warrant investigation?

A. I'm not aware of any.

Q. Are you aware -- actually, one more thing on this document. This was a publicly available document; correct? That's why it's in the Federal Register; right?

A. Yes.

Q. If we go to Page 5, back to Page 5, 3076, Page 5, that right-hand column, I missed a sentence at the very end of the paragraph we were looking at on the right-hand side. It's the sentence before the final sentence. It's -- further down, if you could just scroll down. Right there. A little, a little -- no, stop. A little up. Thanks. That's perfect.

Do you see where it says, where it says, "Moreover, as mentioned above, the responsibility for monitoring and preventing controlled substance abuse is shared by state and federal governments." Do you see that?

A. Yes.

Q. Is that a true statement?

A. Yes.

Q. Now, are you aware that DEA promoted pain relief at various points in time while you were there?

A. I'm aware that -- we never promote pain relief. We just support -- we, we -- I think the statement we've used in the past was we never would want a patient to go without pain relief.

Q. Well, let me ask you this question. Obviously, one of your goals is preventing the abuse of pain medication; correct?

A. Yes.

Q. Did you balance that with the policy of promoting pain relief?

A. Again, we, we told -- we made numerous statements about that saying that patients should get the appropriate medical care to relieve their pain. We've said that over and over again.

Q. I'm focusing on the verbiage I'm using. That was the policy of promoting pain relief; correct?

A. It was a policy -- yeah, I guess if you want to call it that, but it's a policy of treating pain appropriately.

Q. Okay. And that's something -- that policy of promoting pain relief is something you've testified about in Congress; right?

A. Yes.

Q. And, so, just within this document, let's look at what this document says on that point.

If we could go to 3076, Page 4 please. And if you look at the bottom of the left-hand column carrying over to the center column, there's a reference to an interim policy statement published in the Federal Register. Do you see that?

A. Yes.

Q. And that's an interim policy statement from 2004 by the DEA; correct?

A. Yes, I -- if I'm not mistaken, that one was withdrawn from the -- we withdrew that.

Q. And I'm going to come to that. It says, "Chronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper pain medication to patients as medically justified."

Do you see that?

A. Yes.

Q. Okay. And this policy statement covered a lot of things that I'm not going to go through. But I want to focus on these two sentences.

Do you agree that those two sentences remained true throughout your tenure at DEA; the recognition that chronic pain is a serious problem for many Americans and that it is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified?

A. I agree that the second sentence is correct. The first sentence -- I believe they've made different statements about chronic pain and, and -- regarding the number of chronic pain patients and the type of pain that's chronic pain. Over the tenure that I had in the Office of Diversion Control, that's changed considerably. So I don't necessarily agree with that first statement.

Q. Let me just show you a document, Defense West Virginia 2640.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: It might be an appropriate time to quit if you're at a good stopping point.

MR. SCHMIDT: Sure, of course, yes.

THE COURT: We've got to clear things out so I can do another hearing. So we'll be in recess until 2:00.

(Recess taken at 11:56 a.m.)

THE COURT: Okay, Mr. Rannazzisi, you can resume your seat there, sir.

MR. SCHMIDT: May I continue?

THE COURT: Yes.

MR. SCHMIDT: Mr. Rannazzisi, before we pick back up, two housekeeping matters.

First, just if we can for you and the Court, somebody pointed out to me on the break, when I wrote this first line, supply does not drive demand, I left out the word "drive".

Second, I did try to spend time over our lunch break reducing so we can get you out of here and that includes cutting out the exhibit I was about to ask you about. So, let me take up a new topic, if I could.

May I approach to give out MCWV-2174?

THE COURT: Yes.

MR. SCHMIDT: Thank you, Your Honor.

BY MR. SCHMIDT:

Q. You have in front of you MCWV-2174?

A. Yes.

Q. Do you recognize this as a DEA write-up on a regulation that it was issuing during your tenure or a rule that it was issuing during your tenure?

A. Yes.

MR. SCHMIDT: We'd move this into evidence, Your

Honor.

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. Let's just orient us to what we're looking at here. And before we get into this, is it correct that DEA took steps on your watch to make it easier for doctors to prescribe prescription opioids for longer periods of time without seeing the patient in between?

A. It wasn't necessarily the prescription opioids. Actually, this had to do more so with patients who were away at school who were on ADHD medication, if I was not mistaken.

Q. Okay. Well, let's look at what this says. If we go to the first page, it says issuance of multiple prescriptions for controlled substances. Do you see that language in bold? And then it says agency, Drug Enforcement Administration; action, final rule. Do you see that?

A. Yes.

Q. We can actually -- I'm going to switch over on the screen, if I may, because we're done with this board.

And Schedule II controlled substances includes oxycodone, correct?

A. Yes.

Q. After 2014, it included hydrocodone?

A. Yes.

Q. And this rule remained in place throughout your tenure at DEA, correct?

A. Yes.

Q. Let's look at the summary. If we read the summary, it says the Drug Enforcement Administration is finalizing a notice of proposed rule making published in 2006. Do you see that?

A. Yes.

Q. In that document DEA proposed to amend its regulations to, quote, "allow practitioners to provide individual patients with multiple prescriptions" -- and let's just highlight that language -- "allow practitioners to provide individual patients with multiple prescriptions to be filled sequentially for the same Schedule II controlled substance, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that controlled substance." Did I read that correctly?

A. Yes.

Q. So, in simple terms what this did is, you could go see a doctor one time and instead of having to go back within a 90-day window, you could get back-to-back prescriptions to cover you for up to 90 days, correct?

A. That's correct.

Q. And that was any Schedule II controlled substance, correct?

A. Yes.

Q. And that lengthened the period of time that a patient could go while having a controlled II Scheduled substance without having to see their doctor, correct?

A. Yes.

Q. And this change was not limited to any specific practitioners, but applied to all DEA registered practitioners, correct?

A. That's correct.

Q. Dentists?

A. Well --

Q. General practitioners if they had a DEA registration?

A. And if the State allowed it.

Q. Correct.

A. Yes.

Q. So, let me be sure to add that. If the State allowed it and they had a DEA registration, whether they were a dentist or a general practitioner, this extension of time applied to all of them?

A. Yes.

Q. Let's look at Page 7. Do you see where it says conclusion? And in the second sentence it says as DEA noted previously, this rule making was supported by a wide variety

of individuals and organizations, medical professionals, patient advocacy organizations, and patients themselves. To reiterate, the majority of commentators believed this final rule would be beneficial from both physical and financial perspectives, citing the time and money saved due to less frequent -- I'm sorry -- less frequent visits to prescribing practitioners, and the reduced physical toll resulting from the reduced visits. Did I read that correctly?

A. Yes.

Q. What was your role in this rule?

A. I reviewed the rule and gave my input and then it was -- subsequently went through the rule making process.

Q. Did you support it?

A. Yes, I did.

Q. And when you were saying college kids taking ADHD medications, do you understand when it references physical toll, that's talking about pain patients and prescription opioids, correct?

A. Not necessarily.

Q. Is there a physical toll from college kids having to go to their doctor?

A. Well, if they're four states over and they have to go back every month, it would be difficult.

Q. Okay.

A. But that's not the only reason. This -- this

supplemented what the doctors were doing to begin with, which was the doctors were prescribing huge quantities of opioids so that patients wouldn't have to come back for -- every 30 days, especially palliative care, and Hospice care, end of life care. Those people can't come back every 30 days.

So, what the doctors were doing, instead of prescribing a hundred tablets, they were prescribing 300 tablets at that moment in time. We thought that it would not be prudent to have those tablets, if the patient passed, in somebody's medicine cabinet.

So, if you have the do-not-fill, every 30 days it would go back to the pharmacy, and every 30 days that pharmacy would be authorized to fill. But this was all about keeping huge quantities out of prescriptions and there's no quantity limit. Congress never set a quantity limit on a Schedule II prescription. So, they could have prescribed 300 tablets easy. 400 tablets easy.

This cut down the amount of drugs that could be in the house at any time and made sure that the patients would be -- have access to the drugs, yet not keep a huge amount in -- in their medicine cabinets, in their homes, because of the prescriptions. And the same thing with the ADHD kids that were over at school.

Q. So, a few follow-up questions, sir. First question,

this was not limited to palliative care, correct?
A. It was not.
Q. It did not set a pill limit to say we're going to 90 days, but that means you have to have a pill limit, did it?
A. No. There was a pill limit. It's a 30-day -- it's a 90-day supply, if I'm not mistaken. So, there is a pill limit.
Q. It was limited to 90 days, correct?
A. Right.
Q. It didn't limit the number of pills that could be prescribed in those 90 days, correct?
A. Well, if it's a 90-day supply, it would be based on the way it was -- if I'm not mistaken, I haven't read this in awhile, but the way it was written, it would be per prescription. So, the quantity in the prescription, saved in the prescriptions, would dictate the amount.
Q. There was no limit on the prescription amount that could be issued within that 90 days, correct?
A. It's been awhile. I have not read it. But if I remember correctly, the whole reason for this was to limit the amount of drugs per prescription so the doctor wouldn't write for a 90-day supply in one prescription.
Q. I hear what you're saying. My question is simply there was no limit in this rule on the number of prescriptions?

A. Again, if you --

THE COURT: Mr. Ackerman?

MR. ACKERMAN: Asked and answered, Your Honor.

MR. SCHMIDT: I don't think he's answered, Your Honor. He's explained why he was trying to do it. He hasn't answered my question.

THE COURT: Well, go ahead.

THE WITNESS: I don't -- yes, Your Honor.

I don't know because I haven't read this in a long time. So, I could read it and get an idea of what it says, but --

BY MR. SCHMIDT:

Q. All right. Let's do that. Let's go to the bottom of this page, please. And if you look at the very bottom, you can see it says Section 1306.12, very bottom, is revised to read as follows. And then it has on Page 8 the text of the language. Do you see that? Do you see that, sir?

A. Yes. I'm looking at it right now.

Q. And then, on Page 8, it has the new language of the rule. Do you see that?

A. Yes.

Q. There's no limit on pills in that new language, correct?

A. No. I believe there is a limit.

Q. Where does that appear?

A. If you're looking for a 90-day supply, it's based on the instructions. That's why it says a 90-day supply. So, if the instructions are one tablet every -- every six hours, that would be 120 tablets. So, you would get 120 tablets per prescription.

Q. Is there any limit here placed on the number of tablets that could be provided pursuant to an individual prescription up to 90 days?

A. Again, it is my view and the way I looked at it was that 90-day supply was -- pertains to the amount in the prescription based on the instructions in the prescription.

Q. Did it --

MR. ACKERMAN: Your Honor, I feel like we've asked the same question and gotten the same answer now six or seven times and I -- if Mr. Schmidt doesn't like the answer, I'm sorry, but that's clearly this witness's understanding.

MR. SCHMIDT: That's true that I've asked the same question and gotten the same answer. Not one of them has been responsive. But I'll move on. I think the record stands as it is and the witness is refusing to answer.

MR. ACKERMAN: Move to strike that last comment.

BY MR. SCHMIDT:

Q. Let's go to Page 6. We saw on Page 7 that it talked about people in support of this change, correct?

A. I'm sorry. Could you repeat that?

Q. We saw on Page 7, the language we were looking at, that this regulation or this rule making talked about people who supported this change. Do you remember we read that language into the record?

A. Yes.

Q. There were also people who opposed it, correct?

A. Yes. I'm sure there were. There were always people that opposed that.

Q. Let's look at that. Third paragraph from the bottom. It says appropriateness of this rule in view of the extent of prescription controlled substance abuse in the United States. Do you see that?

A. Yes.

Q. And some of the commentators who objected to the proposed rule, among those, quote, "many pointed to the alarming increase in prescription controlled substance abuse in the United States and resulting deaths and harm to the public welfare." Those were comments you received opposing this lengthening of the time that doctors could give prescription opioids for without seeing their patients, correct?

A. Yes.

Q. And then, if we go a little further up, it says possibility of increased pressure on prescribing practitioners and it talks about some commentators and the

second line at the end asserting practitioners might feel undue pressure to prescribe a 90-day supply of controlled substances at each office visit. Do you see that?

A. Yes.

Q. And this rule change was made at a time you were grappling with internet pharmacies, right?

A. Yes.

Q. This rule change was made at a time that you started to see a problem with rogue pain clinics, correct?

A. There were pain clinics out there at the time, yes.

Q. And just -- quick point on rogue pain clinics. Did you ever adopt a rule or a practice where you refused to register doctors if they were in pain clinics?

A. No.

Q. Why not?

A. Because there are pain clinics that are actually not rogue.

Q. Okay. Did you ever refuse to register pharmacies that dispensed prescriptions to doctors working at pain clinics?

A. Refuse or take action against?

Q. Refuse?

A. On an application, you're talking about?

Q. Yes, sir.

A. Well, I wouldn't know if they were taking pain clinic patients unless they were actually registered to be

pharmacies.

Q. That's with I'm taking about. The ones that are registered as pharmacies, did you ever condition their registration on them not supplying -- filling prescriptions from doctors at pain clinics?

A. Any pharmacy registration is conditioned on the fact that if you do fill prescriptions outside the usual course of professional practice and not for legitimate medical purpose and corresponding responsibility they could have their license removed.

Q. I'm asking a little bit of a different question, sir. Did you ever make a rule that you would not register them if they filled prescriptions from any pain clinic?

A. Of course not.

Q. For the same reason you just told me about, right?

A. Yes.

Q. Now, you touched on a topic I wanted to ask you about. You agree with me that the most common, most frequent method of obtaining a pharmaceutical controlled substance for non-medical use is through friends and family for free?

A. No. I -- repeat that question again. I want to make sure I got that one right.

Q. Sure. Of course. The most frequent method of obtaining a pharmaceutical controlled substance for non-medical use is friends and family for free?

A. Yes. I've testified to that based on the opinion of the Administration, but that was not my own personal view.

Q. You've also given presentations on that point, haven't you?

A. That's right. That's the Administration's position.

Q. Did you espouse any views when you were at the Administration that you believed to be false or untrue?

A. What -- to who, to the Administration?

Q. No, to Congress in the presentations you made on behalf of the Administration?

A. I always presented the information that the Administration approved and that was based on a survey. That was based on a survey that I didn't necessarily agree with, but it was their position, so I was the government vehicle to get their message to Congress.

Q. Do you mind answering my question now, please?

A. Yes.

Q. In doing that, did you ever express views you believed to be false?

A. I -- yeah. I presented views that I didn't agree with but, I don't know if they're false or not. It was my opinion. I didn't agree with them, but --

Q. Okay. Well, I don't want to ask you about opinions, so I'm going to focus on truth and not truth. These views -- when you expressed the view that the most frequent method of

obtaining a pharmaceutical controlled substance for non-medical use is friends and family for free, did you believe that was a false view?

A. I didn't express that view. Again, again, that is the view of the Administration. When I testified before Congress, I'm not testifying as Joe Rannazzisi. I'm testifying as the Administration. When I'm going before any kind of public meeting, I'm -- I'm presenting as the Administration, not Joe Rannazzisi.

Q. Let me come back to my question. When you testified before Congress that the most frequent method of obtaining a pharmaceutical controlled substance for non-medical use was friends and family for free, did you believe that to be a false statement?

A. No.

MR. ACKERMAN: Objection, Your Honor. Asked and answered.

THE COURT: Overruled. You may answer.

THE WITNESS: In my opinion, I did not agree with that. I did not agree with that statement. Do I know it's false? No. I don't know it's false, but I did not agree with that statement.

BY MR. SCHMIDT:

Q. Did you ever tell Congress I don't agree with this but this is the DEA position?

A. That's -- that's not how congressional testimony works. Congressional testimony, you're presenting for the Administration for the Department of Justice.

Q. Is the answer to my question no, you never did?

A. No, I never did.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I have some excerpts of a 2013 presentation with your name on it. Do you see that on the cover slide regarding drug trends?

A. Yes.

Q. This is excerpts. If you go to Page 2 of the document --

MR. ACKERMAN: Objection, Your Honor. The problem we have is that defendants don't disclose their documents to us beforehand, so I don't know what's omitted from this document. So, I can't really object to it without finding it among a massive stack.

So, I would object to questioning regarding a portion of a document that, if we can work out the excerpts before the questioning, I think that's a different story. But to just present a witness with a self-selected cherry-picked excerpt of a document is improper.

MR. SCHMIDT: It's for impeachment, Your Honor.

THE COURT: Yeah, overruled.

BY MR. SCHMIDT:

Q. Do you see on Page 2 in this presentation you gave it says most frequent method of obtaining a pharmaceutical controlled substance for non-medical use, friends and family for free? Do you see that?

A. Yes.

Q. And do you know if you gave that -- made that statement at presentations more than once?

A. Yes. That was the Government's position.

Q. At any of those presentations did you say this is the Government's position, but my opinion, I disagree with it?

A. I wouldn't do that. That's not what we're allowed to do.

Q. Did you believe you were saying something false when you said this?

A. No. I -- as I said before, I didn't agree with it, but they had a survey to back it up, so I didn't have a choice but to go with it.

Q. Do you have any contrary data?

A. Yeah, our investigations.

Q. I mean like a study or a survey?

A. No. Just our investigations.

Q. And then the next slide says medicine cabinet and then problem, pharmaceutical controlled substance disposal. Do

you see that?
A. Yes.
Q. And then it says so many drugs in the household, why, and then it gives two reasons. Do you see that?
A. Yes.
Q. One is unreasonable quantities being prescribed. Do you see that?
A. Yes.
Q. And that refers to decisions being made by doctors, correct?
A. Yes.
Q. And do you believe that to be true, that some of the contributions to unreasonable levels of drugs in the household is unreasonable quantities being prescribed?
A. Yes.
Q. And just to be clear, what I understand you to be talking about here is that if -- and I think you touched on it in the context of that 90-day rule, that if you have a lot of opioids given to a given patient, someone else might use them?
A. Yes.
Q. Someone might take them. They might steal them. They might give them away. And that can be -- that is diversion?
A. Well, technically, yes.
Q. Every one of those is diversion, right, stealing,

giving away, selling?

A. Well, if it's in the patient's hands, once it's in the patient's hands, if it's stolen, it's just -- it's stolen. It's not necessarily diversion.

Q. Okay, fair enough.

A. Because the patient is not within the closed system of distribution.

Q. And that form of diversion or theft can occur even if a distributor, or a pharmacy, or a manufacturer does what they're supposed to do, right? They could fill a good faith prescription written for an unreasonable quantity, or even a reasonable quantity, and some could be stolen, given away, sold?

A. What did you say initially? Just -- I didn't hear the first part of the question.

Q. The first part of my question was you can have a prescription written in good faith where, as to that prescription, the doctor does what they're supposed to do, the pharmacy does what they're supposed to do, the distributor does what they're supposed to do, and the manufacturer does what they're supposed to do, and it still gets sold, stolen or given away?

A. Yes.

Q. The second point you have on this slide is insurance rules. Do you see that?

A. Yes.
Q. What are you referencing there?
A. Some insurance companies require a 90-day supply, 60-day supply, depending on the insurance company for filling, but not necessarily controlled substances.
Q. And, actually, one more question about this document. I apologize. I want to make sure I just have this.

When you told Congress and others that the most frequent method of obtaining a pharmaceutical controlled substance for non-medical use was friends and family for free, you understood that to be the position of the DEA, correct?
A. It was the position of the Administration so, yes.
Q. In making public statements about prescription opioids, there were occasions where you would refer doctors to standards adopted by their State Medical Boards, correct?
A. We always refer the doctors to their State Medical Boards because only the states dictate the practice of medicine.
Q. In fact, you took the position that the DEA encourages physicians to seek guidance from the State Medical Boards, correct?
A. Again, yes. The states dictate the practice of medicine. So, yes, that's been said before.

MR. SCHMIDT: And I didn't ask to approach. I'm

sorry, Your Honor.

BY MR. SCHMIDT:

Q. Do you recognize Exhibit P-9270 as an article that you wrote that was published in June of 2000 in a publication called Clinical Pharmacology and Therapeutics? My question, sir, simply is do you recognize this article as an article you have written?

A. I wrote a lot of articles. My name is on it, so I'm sure I wrote it, but I just don't recall this one.

MR. SCHMIDT: We'd move into evidence Exhibit P-09270.

MR. ACKERMAN: Can I have a minute to consult with my colleagues, Your Honor?

THE COURT: I'm sorry?

MR. ACKERMAN: I just need to minute to consult with my colleagues.

THE COURT: Yes. Yes.

MR. SCHMIDT: And if I can just ask one question while you're consulting, just for the record.

BY MR. SCHMIDT:

Q. If you look at the bottom, do you see under your name it says -- it's not just any J. T. Rannazzisi. It's J. T. Rannazzisi from the Office of Diversion Control Drug Enforcement Administration, Alexandria, Virginia. Do you see that?

A. Yes.

Q. And there's a DEA -- I guess it's an e-mail address where you --

MS. SINGER: Excuse me, Mr. Schmidt. Could you just give us one minute before you ask the question?

MR. SCHMIDT: Yes. Sure. Of course.

MS. SINGER: Thank you.

(Pause)

MR. ACKERMAN: So, Your Honor, we have no objection to introducing medical literature provided that we are afforded the same courtesy.

MR. SCHMIDT: I don't see how --

THE COURT: That depends entirely on what the medical literature is, Mr. Ackerman.

MR. ACKERMAN: I understand. We have no objection to this document.

MR. SCHMIDT: Okay.

THE COURT: You want it admitted, Mr. Schmidt?

MR. SCHMIDT: Yes, please, Your Honor.

THE COURT: All right. It's admitted.

BY MR. SCHMIDT:

Q. All right. So, let's just look at that language that I was reading you. It was on the right-hand side. Do you see where you wrote in this article, this is a pharmacology and therapeutics article, that the DEA encourages physicians to

seek guidance from their State Medical Boards? That's that proposition we've been discussing, correct?

A. Yes. We've gone over that in the past, yes.

Q. And that's something you did throughout your career at DEA, correct?

A. When speaking to physicians groups, yes.

Q. Let's look at an example of that.

MR. SCHMIDT: Your Honor will recall that we used a book earlier and I believe Mr. Hester promised we would give the Court a hard copy of the book, so I want to carry through on that promise, if I may.

THE COURT: Yes. I would like to have some more things up here.

MR. SCHMIDT: This one is slender. It's MCWV-2111 and it's in evidence.

And then there's paper copies if anyone wants a paper copy of the pages.

BY MR. SCHMIDT:

Q. There's been testimony in this case that this book was sent by the Medical Boards of 13 states, including West Virginia, to every doctor in those 13 states, including West Virginia. Is that something that you were aware of when you told doctors to look to the guidance they received from State Medical Boards?

A. I know this book has been used in certain areas of the

country. I didn't know that the Medical Boards were sending the books to all the doctors.

Q. Okay. But you knew it was being used?

A. This book?

Q. Yes.

A. This book has been around for awhile, yes, sir.

Q. And I didn't give you a hard copy. I apologize for that. Do you want my copy or do you want a paper copy? I can give you just --

A. A paper copy is fine.

Q. Okay.

THE COURT: He can have mine, Mr. Schmidt.

MR. SCHMIDT: We desperately want Your Honor to have it.

BY MR. SCHMIDT:

Q. All right. Let's just look at a couple of pages of this. If we go to Page 9 of the book, which is Document Page 15, do you see in the upper right corner there's some bullets? Tell me when you're there, sir.

A. I'm on Page 15.

Q. You see the first bullet says patients should not be denied opioid medication except in light of clear evidence that such patients [sic] are harmful -- such medications are harmful to the patients? Do you see that language?

A. Yes.

Q. Were you aware at the time you referred doctors to State Medical Boards that statements like this were being sent by Medical Boards to doctors in at least 13 states?

MR. FARRELL: Objection, Your Honor. I think that misstates the testimony.

THE COURT: Overruled.

BY MR. SCHMIDT:

Q. Were you aware of that, sir?

A. No. Like I said, I wasn't aware that this book was being passed out by the Medical Boards.

Q. Okay. Go to Page 94 of the book. Do you see where there's a heading Federal Guidelines For Prescribing Controlled Substances? Do you see that heading?

A. Yes.

Q. And do you see -- if you just kind of scroll through there, do you see reference to the 2006 policy statement that you spent some time talking about earlier today?

A. Yes.

Q. And then if we continue on to the next page, Page 95, do you see that there's -- this came out before the 90-day rule we were just talking about was finalized, but do you see there's discussion of that rule being proposed?

A. Okay.

Q. Now, you said -- I'm not going to go through the rest of this book. I'm going to wrap up just with a couple of

questions.

When you were at DEA, you said you knew about this book. Did you ever -- you or your colleagues at DEA ever issue any kind of statement correcting anything you believed to be wrong in this book?

A. No. DEA did not get involved in medical practice.

Q. Do you see on the cover it says Federation of State Medical Boards?

A. Yes.

Q. On multiple occasions you've relied on guidelines from the Federation of State Medical Boards, correct?

A. Yes.

Q. And, in fact, one of those occasions is actually referring to distributors to the Federation of State Medical Boards, correct?

A. I'd have to see it.

Q. All right.

A. Referring to the internet pharmacy? I don't -- I would have to see what you're referring to.

Q. Fair enough. Let me help you out. Let's pull up P-1205, which is in evidence. I think it is a document you were shown, so you should have it in your stack, and it is the distributor slides. And let's go to Page 9 of that document.

And do you see that there is reference to -- in giving

guidance to distributors, there's reference to the Federation of State Medical Boards as something distributors can look to in understanding medical need?

A. Okay.

Q. That's guidance you gave to distributors about understanding medical need, correct?

A. Yeah. Because we're talking about the model guidelines of internet, yes.

Q. I want to touch very quickly on the other participants in the closed system starting with pharmacies. Pharmacies are also required to have a DEA registration, correct?

A. Yes.

Q. They're also required to renew it periodically?

A. Yes.

Q. Why is that?

A. Again, every three years so we can do background and make sure that they are indeed licensed appropriately and have not had any disciplinary action.

Q. Are you aware of any instance from your work at DEA where any one of the three distributors in this case supplied controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA?

A. No.

Q. Are you aware of any instances from your tenure at DEA where one of the defendants supplied prescription opioids to

a DEA licensed pharmacy in Huntington or Cabell that the DEA had warned the distributor not to supply?

A. Not that I'm aware of.

Q. You talked for a bit yesterday about whether distributors should require certain information from pharmacies or not do business with them. Do you remember that?

A. Yes.

Q. Have you ever made it a condition for registration of pharmacies that in order to be registered they had to give distributors certain categories of information?

A. No.

Q. For example, did you ever say if you're going to be registered as a pharmacy, you've got to share dispensing data or doctor information with distributors?

A. No, we didn't tell them that.

Q. Did you ever tell distributors as a condition of registration that they had to get that kind of data from every pharmacy or refuse to do business with them?

A. No. That would be part of their due diligence. That's up to them.

Q. Let's talk about manufacturers. DEA must also register manufacturers for them to be able to make controlled substances, correct?

A. Yes.

Q. Manufacturers are the ones responsible for studying the safety and the benefits of prescription opioids and other medications that they make, correct?

A. Yes.

Q. And they're the ones who obtain FDA approval for new prescription opioids, correct?

A. Yes.

Q. And I'm not going to ask you too much about the FDA, but do you have an understanding that at least when it came to prescription opioids, the FDA was only supposed to approve a prescription opioid if they determine that the benefits outweigh its known and potential risks for the intended population?

MR. ACKERMAN: Objection to scope, Your Honor. This is --

THE COURT: Overruled.

BY MR. SCHMIDT:

Q. Do you want me to re-ask it?

A. The FDA's approval process is on safety and efficacy.

Q. And they've got to determine that the safety -- that the benefits outweigh the risks, right?

A. I believe that's built into it, safety and efficacy, yes.

Q. Are you aware that the physician warnings that manufacturers were required to provide for the prescription

opioids warned doctors that they had a risk of abuse and addiction?

A. In the literature? I'm sure it's in there, yes.

Q. Are you aware of any distributor in this case that distributed opioids in Huntington or Cabell that were not approved by the FDA?

A. I'm not aware of any.

Q. Are you aware of an instance where the DEA ever told a distributor in this case not to do business with the DEA registered manufacturer?

A. I -- I don't have any information on that.

Q. Okay. Let me ask you just a few more questions on distributors and then I'll turn to a different topic.

Distributors aren't authorized to write prescriptions, correct?

A. That's correct.

Q. They don't evaluate a patient's legitimate medical need for opioids in terms of deciding whether the opioids are appropriate for that patient, correct?

A. That's correct.

Q. They can't second-guess legitimate medical decisions by prescribers, correct?

A. I don't understand when they would be questioning a legitimate medical prescription.

Q. And they don't have access to individual patient

medical records because of privacy laws, correct?

A. They wouldn't have access to that.

Q. There's been discussion in this case about a term "know your customer's customer". That's not a term you were familiar with during your time with DEA, correct?

A. No. "Know Your Customer", not "Know Your Customer's Customer".

Q. You recognize that distributors play an important role in insuring an adequate and uninterrupted supply of prescription opioids?

A. Yes.

Q. It's important -- it's an important role in terms of them being able to move those drugs downstream and ensure that pharmacies and hospitals have those drugs, correct?

A. Yes.

Q. And that's important because if a patient doesn't get the medication they need, there's a breakdown in the system, correct?

A. Yes.

Q. And that role is a similar role, or a similar interest, a similar purpose, to the DEA in ensuring an adequate supply, correct? Distributors are part of that process of ensuring an adequate supply?

A. Yes.

Q. You agree that it's critical for patients who have a

medical need for prescription opioids to have access to them?

A. Yes.

Q. A couple small points. During your ten years at DEA, you never told distributors to retain due diligence files on all of their customers for all time, correct?

A. I personally did not, no.

Q. You can't identify anyone at DEA who told that to distributors, correct?

A. No. It's just common sense that if they're doing due diligence and they're maintaining files, they would maintain files for the duration of that customer's business relationship so they could see and reach back and look at what the prescribing patterns were from the beginning all the way up to the present.

Q. While you were at DEA you recognized that ARCOS data was helpful to the agency in generating leads for investigations, correct?

A. Yes.

Q. Registrants requested ARCOS data from DEA, but DEA declined to share it, correct?

A. Yes. We were -- we were instructed that we could not share it, yes.

Q. Do you know that DEA has not been required to give distributors limited access to ARCOS?

A. I do from the deposition, the last deposition, yes.

Q. Did you ever support giving distributors more access to ARCOS than they were allowed or the access that they enjoy today?

A. It wasn't a question of whether I supported it or not. It's a question of what I was allowed to do during my tenure and the answer is no.

Q. Did you ever take steps to try to grant greater access?

A. Again, we're getting into internal deliberate process about what we can and can't do.

Q. All I'm asking you, sir, is if you took any such steps. I don't want to hear about discussions with people.

A. We --

Q. I want to know -- let me finish, please. I just want to know if you took any steps to try to grant greater access to ARCOS data when you were at DEA?

MS. SINGER: Objection, Your Honor. I think this is the same issue that defendants were raising yesterday if we can't probe on redirect the reasons for any decision making that leads to an unbalanced and unfair situation where they illicit testimony that can't be fully explored.

THE COURT: Well, the question was if he took any steps to try and grant greater access to ARCOS. I'm going to let him answer that question.

THE WITNESS: I personally did not take any steps.

BY MR. SCHMIDT:

Q. I'm going to close out with one topic. I want to talk about some of those DEA powers that you talked about in your direct examination. And I want to actually put something in front of you and ask you about it, if I can, because it will frame some of my questions a little more easily.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: For the record, this is MCWV-1081. It's testimony from July, 2006 before the Subcommittee on the House of Representatives. Do you see that?

A. Yes.

Q. And if you go to Page 61 -- I'm sorry -- actually, 63 in the lower corner. Wait. 65, I'm sorry. 65 in the lower left corner. Do you see that?

A. That's Page 65.

Q. Do you see your prepared statement?

A. Yes.

Q. All right. I'd like to look at Page 72, please, in the lower left corner within your prepared statement. And here's what I would like to ask you about, sir.

A. Okay.

Q. It says in the third full paragraph, do you see where it says the CSA, the Controlled Substances Act, includes seven major controlled mechanisms? Do you see that?

A. Yes.

Q. And then it lists them. Do you see that?

A. Yes.

Q. And is that an accurate list of different control mechanisms that the CSA grants the DEA?

A. No. That -- that seems to be accurate.

Q. Okay. First one is scheduling. That's Schedule II, III, IV, et cetera?

A. Yes.

Q. And the second one is registration, correct?

A. Yes.

Q. And that's registration of all the participants in the closed system, correct?

A. Yes.

Q. I'm going to skip a couple. The last one is investigational authority, correct?

A. Yes.

Q. And then if you go to actually the third one, it's quotas, correct?

A. Yes.

Q. And then you talked yesterday and we talked a little bit today about your power to enact regulations when appropriate, correct?

A. Yes.

Q. And you can also give guidance, correct?

A. Yes.

Q. All right. I want to ask you about those four points, please. Before I leave this document, if we look at the next sentence, these mechanisms allow DEA to monitor and regulate a controlled substance and its movement. Do you see that?

A. Yes.

Q. Is that true?

A. Yes.

Q. In the case of the most potentially dangerous drugs in Schedule II, we register all persons who handle them. We inspect the documentation of their distribution. We control their import and export. And we control the amount produced, bought, sold, and otherwise transferred. Do you see that?

A. Yes.

Q. And all of that is true, correct?

A. Yes.

Q. So, let's go through those categories very quickly.

A. Okay.

Q. First, registration. And I can show you that there's -- this information. Are you aware that the DEA website tracks the number of registered pharmacies, registered practitioners, over time?

A. I've seen slides to that effect, but I haven't seen

them in awhile, so --

Q. Do you take any issue with the fact that the number of DEA registrations issued to pharmacies in West Virginia went up by about a hundred between -- or 20 percent between 2005 and 2015? Do you take any issue with that?

A. I wouldn't know.

Q. Okay. Well, let me show you then.

MR. SCHMIDT: And may I approach, Your Honor? Two single page documents.

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, Exhibit MCWV-2183 is a printout from the Diversion Control Division Registration -- Registrant Population by State and Business. Do you see that?

A. Yes.

Q. And it allows you to select a state that that box that says West Virginia and it allows you to select a time period. It looks like we actually chose later, August -- August, 2006. Do you see that?

A. Yes.

Q. And there's 513 DEA registered pharmacies. Do you see that?

A. Yes.

Q. And 5,446 DEA registered practitioners. Do you see that?

A. Yes.

Q. If you go to the next slide, or the next document, MCWV-2197, it's the same web page, also for West Virginia, this time for October, 2015. And do you see that the pharmacies have gone from 513 to 600, nearly a hundred?

A. Okay.

Q. And that practitioners have gone from 5,446 to 6,656, more than a thousand? Do you see that?

A. Yes.

MR. SCHMIDT: We'd move these two into evidence, Your Honor.

THE COURT: Any objection?

MR. ACKERMAN: No objection.

THE COURT: They're both admitted.

BY MR. SCHMIDT:

Q. My question on this to you simply is I take it your judgment at DEA was that that increase in both pharmacy and doctor registrations both by somewhere in the order of 20 percent was appropriate given medical needs and legitimacy of those pharmacies --

THE COURT: Let me interrupt and ask you a question. What's a mid-level practitioner on that chart?

THE WITNESS: Your Honor, that would be a physician's assistant, advanced practice nurse, and certain -- podiatrists.

THE COURT: And they're authorized under some

circumstances to prescribe opioids?

THE WITNESS: Yes, sir. The way -- the way that the Controlled Substances Act works is we look to the State. If the State grants them the ability to prescribe controlled substances, we're required -- unless they have some kind of felony in their background, we're required to give them a license.

BY MR. SCHMIDT:

Q. And just to complete the record, that category for mid-level practitioners, more than doubled from 910 to 2,023, correct?

A. Yes.

Q. I take it you had view that this growth in registrations from mid-level practitioners, practitioners and pharmacies was appropriate?

A. Well, the State dictates the practice of medicine, the practice of pharmacy, and the oversight of the mid-level. So it's what the state believes is appropriate, not what DEA believes.

Q. Well, in terms of DEA granting them a separate registration, did DEA believe it was appropriate to separately register them under its standards?

A. As long as they met the appropriate licensure requirements under the State, DEA has really no choice but to -- to register them.

Q. I want to focus on -- we -- you and I talked earlier about the .01 percent of the doctors that DEA takes action against on an annual basis. Yesterday you were asked about 16,000 doctors. Do you remember that testimony?

A. Yeah. I think it was a range, but --

Q. Yeah. You agree that it's a good thing to require DEA criminal background investigations of all new registrant applications, correct?

A. There should be a background investigation done, yes.

Q. There was a period of time where you didn't do any background checks either with the initial registration of a prescriber or subsequent registration of a prescriber, correct?

A. There was a time where we -- there was a time where we were not given access to certain databases and we had to go through private -- private means to get that background information, yes.

Q. Well, I think that's a little different than what I asked. Let me try one more time.

Did there come a point in time where you didn't do any background checks either with the initial registration of a prescriber or a subsequent registration of a prescriber? Yes or no, if you can?

A. I don't recall. I -- I know there was a time where there was an issue with that. I just don't recall the exact

time and the length of that time.

Q. Can we cull up the July 16th, 2020 transcript at Page 129, Lines 2 through 7?

MR. ACKERMAN: For the record, Your Honor, we'd renew our objection to use of this transcript, which is not the MDL transcript.

THE COURT: All right. Overruled.

BY MR. SCHMIDT:

Q. Question, then there came a point in time where you didn't do any background checks, either with initial registration of a prescriber or subsequent registration of a prescriber, correct? And your answer was no. We relied on the State. Did I read that correctly?

A. Yes. And I said we relied on the State, but there were other things that occurred, but that's -- that's absolutely correct. We did rely on the State.

Q. And you're aware of government findings from after your watch that you relied on the good faith of applicants to disclose relevant information, correct?

A. Yes.

Q. And that's a true statement, that you relied on the good faith of applicants to disclose relevant information, correct?

A. And the State, yes.

Q. Do you know with specificity what types of background

checks West Virginia did?

A. I don't know.

Q. Let me ask you, does prescriber registration from the DEA, in your view, provide meaningful protection to the public against improper prescribers?

A. Yes.

Q. Let's go to the second category, investigations. Do you know there are times where distributors told the DEA they were cutting off pharmacies, correct?

A. I'm sorry. Can you repeat, please?

Q. Of course. Do you know there are times, occasions, when distributors told the DEA that they were cutting off pharmacies, correct?

A. Yes.

Q. And of the instances where that happens, you don't know what percentage of those pharmacies DEA actually investigated, correct?

A. No. As I sit here, no.

Q. You can't tell me if it was 10 percent, 50 percent, 1 percent, correct?

A. I don't know.

Q. You can't tell me what percentage of the tens of thousands of suspicious orders that DEA received on your watch that actually directly led to an investigation, correct?

A. I don't -- I don't know and I don't think I could -- I don't think I could tell you that even if I did know.

Q. Okay. I'll stand on your you don't know. Do you know whether it was more than one percent of suspicious orders reported that resulted in an investigation? Do you know?

A. I don't know.

Q. Okay. Can you identify any suspicious orders reported for pharmacies in Huntington or Cabell? And I don't want you to tell me which ones, but can you any that resulted in investigations?

A. I don't know.

Q. You're aware that DEA has been criticized for its use of Suspicious Order Reports that have been submitted by distributors, correct?

A. Could you repeat that, please?

Q. Are you aware that DEA has been criticized by the Office of the Inspector General for its use of suspicious orders submitted by distributors?

A. Can you tell me which report you're referring to? Is that the 2019 report?

THE COURT: Just a minute.

Mr. Ackerman?

MR. ACKERMAN: Actually, let the witness clarify first because I think that will explain my objection.

THE COURT: All right.

THE WITNESS: 2019 report?

MR. SCHMIDT: Yes.

MR. ACKERMAN: All right. So, Your Honor, counsel is now beginning to question regarding a 2019 Office of the Inspector General Report. That report was issued after the MDL deposition. It was not addressed in the MDL deposition. So, we'd offer our scope objection consistent with your ruling on the permissible scope of Mr. Rannazzisi's testimony with respect to this line of questioning.

MR. SCHMIDT: It relates to his tenure, sir.

THE COURT: Pardon me?

MR. SCHMIDT: It relates to his tenure, Your Honor.

THE COURT: Yes. Overruled. This is cross examination. I'm going to allow it.

By MR. SCHMIDT:

Q. Are you aware of that 2019 report that takes issue with how DEA dealt with Suspicious Order Reports on your watch?

A. I remember there was a section in there about suspicious orders, yes.

Q. And one of the findings from that report, do you recall, is that DEA Field Division staff did not receive access to the Suspicious Order Reporting System until 2017, after your tenure; do you recall that?

A. No. I -- if you can --

Q. Of course.

A. I would like to read that.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: This is in evidence.

MR. FARRELL: Judge, on behalf of Cabell County and to save us some time, does this open the door for re-direct on this document with this witness?

THE COURT: Well, we'll cross that bridge when we get to it, Mr. Farrell.

MR. FARRELL: Thank you.

BY MR. SCHMIDT:

Q. And do you recognize this document as the one we've been discussing?

A. Yes.

Q. And if you look on Page 36, it says in the middle paragraph five lines, six lines, seven lines down, one diversion program manager.

MR. SCHMIDT: Can you highlight that language from the middle paragraph, please?

BY MR. SCHMIDT:

Q. Described the SORS database as a "joke", noting that DEA Field Division staff did not receive access to the SORS database until 2017, nearly ten years after it was created. Are you aware of that finding?

A. I'm sorry. Which page are we on here?

Q. It's little numbered Page 36.

A. 36?

Q. In the lower left. Were you aware of that finding, sir?

A. Yes. That was from one diversion investigator, one diversion program manager, who said that.

Q. Your understanding is that when there was follow-up on Suspicious Order Reports it would be done by the local Field Office agents, correct?

A. Yes.

Q. Are you aware of any suspicious orders -- well, I think I probably asked this.

Let's move to the next category. And I'm actually going to jump to number 4, regulations and guidance.

Could we cull out P-34, which is a copy of your 2007 letter? And I'm just going to point you to specific language. If we go to the second paragraph of your letter and the second last sentence. Accordingly, DEA does not approve -- wrong sentence. The one before, please.

Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Do you see that?

A. Yes.

Q. That was your view throughout your tenure at DEA,

correct?

A. Yes.

Q. Are you aware of any of your predecessors stating that view in writing in a document you could point us to?

A. I -- I don't -- I can't recall if there was or was not.

Q. Now, let me focus on your watch, 2005 to 2015. I believe you've covered this, but I need to make sure I've covered it. On your watch you made clear that how a distributor created a Suspicious Order Monitoring System was for them to figure out, correct?

A. They were required to create their own system, yes.

Q. You refused to approve individual suspicious order monitoring systems, correct?

A. We weren't authorized to approve suspicious order monitoring systems.

Q. While you were at the DEA you took the position that it was up to the distributors to figure out whether an individual order was suspicious or not, right?

A. It was up to the distributor to determine what's suspicious and what's not.

Q. You took the position that it was up to the distributor to figure out whether to ship an order or not, correct?

A. That's correct.

Q. And you took the position that it's up to the distributor to figure out whether to increase thresholds for

individual pharmacies, correct?

A. We never talked about thresholds with the distributors. It's not -- it was the position of the Drug Enforcement Administration. All of these things that you just mentioned were the Drug Enforcement Administration's position.

Q. That they had figure out their own thresholds, correct?

A. Yes.

Q. You never told distributors that if you take specific steps in your diligence programs, that would be compliant, correct?

A. I don't follow your question.

Q. Did you ever say to distributors if you take these specific steps in your diligence, that will be compliance?

A. No.

Q. You never told distributors that if you used these criteria to try to assess suspicious orders and anytime you see an order that triggers these criteria and you report it to the DEA, you will be meeting your suspicious order reporting obligations, correct?

A. I don't recall saying that.

Q. And I think you touched on this yesterday. You had a policy of not sharing with distributors when you were investigating a pharmacy customer of theirs, correct?

A. We're not authorized to share investigative information.

Q. And I think you said due process concerns for the pharmacy, correct?

A. Due process, but also internal Justice Department. We can't confirm an investigation.

Q. So, if a distributor asked one of your agents should we be worried about this pharmacy we're supplying and you were conducting an investigation of that pharmacy let's say for something horrible like exchanging drugs for sex, that would not be disclosed to the distributor, correct, under this policy you've referenced?

A. We would have to seek guidance from the U. S. Attorney or the Department of Justice.

Q. Absent getting that guidance, you would not share that information, correct?

A. That's -- that's correct.

Q. And you understand that DEA investigations of doctors and pharmacies can, in some instances, take years and years and years?

A. That's correct.

Q. And the time you mentioned in your examination, the one time you mentioned where you learned that one of your agents was doing that, was sharing a list of, hey, watch out for these pharmacies, you told that agency to stop that, correct?

A. Well, didn't say watch out for these pharmacies.

That's not what was in the e-mail. The e-mail basically listed pharmacies and said these pharmacies were cut off by another distributor.

Q. The one time that happened you told that agent to stop, correct? You stopped that practice, correct?

A. That's correct.

Q. It was commonplace for distributors like McKesson, and ABDC, and Cardinal to come in and give briefings to the DEA, correct, about their programs?

A. I don't know if it's commonplace, but I know they come in.

Q. Well, let me ask it this way. Is it true that registrants come in and give briefings to the DEA all the time?

A. Registrants.

Q. Okay. And that has included occasions where the defendants in this case come in and give briefings, correct?

A. Yes. Defendants have been at the headquarters, yes.

Q. We talked about some of the presentations in 2008. After that point in time, you're aware that distributors continued to ask for guidance from DEA?

A. I was aware later on that they did, but it was through liaison policy, which is normal. That's what normally happens.

Q. For example, you know that in June of 2011,

distributors sent DEA a letter asking for guidance on suspicious order monitoring and reporting through their Trade Association?

A. Yes.

Q. And DEA did not answer that letter, correct?

A. That's correct. We were directed not to answer that letter.

Q. Distributors sent another letter asking for guidance two years later, in July of 2013, regarding things like diligence and suspicious order reporting through their Trade Association, correct?

A. That's correct.

Q. And, again, they actually did that in connection with a planned meeting with DEA, correct?

A. I don't know about that, but they did send that letter and, again, we were directed not to answer that letter.

Q. Are you aware that the DEA cancelled the meeting and ignored the letter?

A. Well, we were directed not to answer the letter and I'm sure the meeting was cancelled. If there was a meeting, then I'm sure it was cancelled.

Q. Do registrants have a right to expect responses to written, electronic or telephonic requests from the DEA?

MR. ACKERMAN: Objection.

THE COURT: What's the objection?

MR. ACKERMAN: Foundation, argumentative, outside the scope.

MR. SCHMIDT: One of the road map stops was guidance, Your Honor, and I'm -- I'll lay a foundation.

MR. ACKERMAN: But the question wasn't about DEA's guidance. It was about whether respondents have -- about respondents' expectations.

THE COURT: Yes. The question was do registrants have a right to expect a response. You have to lay a foundation for that one, Mr. Schmidt.

BY MR. SCHMIDT:

Q. Do you understand that the DEA believed that DEA registrants have a right to expect responses to written electronic or telephonic requests?

A. DEA registrants, yes, they have a right, but not advocacy groups.

Q. Do you have an understanding that DEA registrants have a right to expect guidance regarding the CSA and its regulations?

A. Yes, but again, the individual registrants can come in and request that guidance. The advocacy group doesn't really represent all of the distributors.

Q. You're aware that government watchdogs made findings that DEA should give more guidance to distributors while you were at DEA, correct?

A. Yes.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've given you a report from the GAO, June, 2015. More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, DEF-WV-2181. This report came out on your watch, correct?

A. Yes.

Q. And you're aware of this report, correct?

A. Yes. I wrote the response to it.

Q. And I was just going to point that out. If we look at Page 82, you actually wrote a response to a draft of it, correct?

A. Yes.

Q. Let's go to Page 82, please. I'm sorry, page 89. And there we see your response, correct?

A. Yes.

Q. All right. Let's look at Page 34 of this report. And I'm using the number in the lower left corner again. This is shortly before you left DEA, correct?

A. Yeah. About three or four months before.

Q. They state a guidance document for distributors -- I'm looking in the first full paragraph. A guidance document

for distributors similar to the one offered for pharmacies and practitioners could help distributors further understand and meet their roles and responsibilities under the CSA for preventing diversion, though the document may not need to be as detailed. Did I read that correctly?

A. Yes.

Q. Were you aware of that finding?

A. When I read that, yes, I was.

Q. Okay. If we skip a sentence, they give an example. They say DEA could -- it's actually two lines up and I didn't skip a sentence. I started halfway through the sentence because there's a comma where it looks like there would be a period or something. DEA could, for example, provide guidance around best practices in developing suspicious order monitoring systems. Were you aware of that finding?

A. Yes.

Q. DEA could also enhance its proactive communications with distributors. And then they give some examples. Do you see that?

A. Yes.

Q. And then let's skip to the next sentence. Such steps are key to addressing distributors' concerns, as without sufficient guidances and communication from DEA, distributors may not be fully understanding or meeting their

roles and responsibilities under the CSA for preventing diversion. Do you see that?

A. Can I read that one more time?

Q. Of course.

A. Thank you.

Yes. I see that.

Q. And then they say, additionally, in the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by the customers, I.e., pharmacies and practitioners, which can negatively impact pharmacies and ultimately patients' access. Do you see that?

A. Yes.

Q. Do you agree with the idea that if thresholds are set too low they can negatively impact pharmacies and ultimately patient access?

A. Well, I -- I can't agree or disagree because I don't know how you're setting the threshold and I don't know the customer. I don't know where the customer sits. So, no, I can't agree or disagree.

Q. Fair. Let's go to their recommendations on Page 51. Do you see that they have three recommendations for executive action? The second is solicit input from distributors or associations representing distributors.

That would be a group like HDMA, correct?

A. Had, yes.

Q. What you referred to as an advocacy organization?

A. That's what it is.

Q. And develop additional guidance for distributors, regarding their roles and responsibilities for suspicious orders monitoring and reporting. Do you see that?

A. Yes.

Q. I take it -- well, let me -- let me ask you one more question.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, I've put in front of you MCWV-2208. Do you see that? It's dated December 20th, 2016, U. S. Department of Justice. And if you look at the Bates number in the bottom corner, you can see that this was provided to us by the DEA. Do you see this document?

A. Yes.

MR. SCHMIDT: I'd move this into evidence, Your Honor.

THE COURT: Any objection?

THE WITNESS: No. Have I seen this document?

MR. SCHMIDT: No. I said do you see this document?

THE WITNESS: Oh, do I see it? Okay.

MR. SCHMIDT: I'm about to ask you that question but, first, I want to move it into evidence.

MR. ACKERMAN: I don't think he's laid the foundation because the only question was do you see this document.

MR. SCHMIDT: It's a U. S. Department of Justice letter to the Government Accountability Office produced by the DEA in this litigation. I think it's a government record.

THE COURT: Mr. Farrell?

MR. FARRELL: Yeah. I don't believe this is -- I'm not saying he can't get the foundation to it, but I don't think he's laid it.

MR. SCHMIDT: I'm trying to -- I'm trying to short-circuit, but let me see if I can help.

BY MR. SCHMIDT:

Q. Do you see it relates to in the subject line Re: DEA Status Reports? And then it references that GAO Report you were just looking at. Do you see that?

A. Yes.

Q. And do you see it's written to the Director of Healthcare and the Government Accountability Office, the Office of the Government that wrote that report we were just looking at?

A. Yes.

Q. And do you see in the first line it says the Drug Enforcement Administration provides the following status reports on actions taken to address the GAO Report? Do you see that?

A. Yes.

MR. ACKERMAN: Your Honor --

MR. SCHMIDT: We'd move it in as a government record, Your Honor.

MR. ACKERMAN: So, Your Honor, this is after his tenure at the DEA. There's no -- Mr. Rannazzisi hasn't testified to anything other than the contents of a document that counsel hasn't established he saw before sitting on the stand today. All that he testified to was that the document says what's on its face.

MR. SCHMIDT: And, Your Honor, what I think is appropriate is for me to be able to move this in as a business record, as a government record, and then I will ask Mr. Rannazzisi if he's seen it. If he hasn't, I'll move on, but I think it's important to --

THE COURT: Have you laid the basis for it as a government record as an exception to the hearsay rule?

MR. SCHMIDT: I believe we have, Your Honor. Under Rule 806 -- I'm sorry. Under Rule 803 --

MR. FARRELL: Judge, to save you some time, our

objection is premised upon maintaining the scope of Mr. Rannazzisi as a fact witness and if the defendants believe that documents produced by the DEA are self-authenticating and admissible, we agree, and note that there are many such attached to the Prevosnik deposition.

MR. SCHMIDT: Your Honor, I have not looked at those documents. I move this document in. And I'm moving it in under 803 --

THE COURT: (8).

MR. SCHMIDT: 803(8), yes. Thank you. It sets out the Office's activities. It sets out a matter observed while under a legal duty to report. And it's factual findings from a legally authorized investigation insofar as this is the DEA responding to a GAO investigation with their update on steps taken as a result of that. It's all three clauses.

MR. ACKERMAN: The problem here, Your Honor, is that that's Mr. Schmidt's testimony. There's no testimony from a witness as to -- as to what this is. So, it's different from the documents that Mr. Rannazzisi saw during his tenure at the DEA and can testify to. There's not a -- there's not a foundation from a witness.

MR. SCHMIDT: And I'll note, too, I believe the plaintiffs have given us designations for DEA witnesses and includes this as an exhibit. So, I think we can stipulate

that it comes in. You want it for Mr. Strait (phonetic). We want it for -- for the record. And then, I'll ask Mr. Rannazzisi if he knows about it. If he doesn't, I'll move on.

MR. ACKERMAN: I'm looking at the people who know more about this than I do.

THE COURT: I'm going to sustain the objection to this one on the basis of a lack of proper foundation through this witness.

MR. SCHMIDT: May I just ask him if he's seen it before?

THE COURT: You can use it to ask him some questions and --

MR. SCHMIDT: Okay.

BY MR. SCHMIDT:

Q. Let's go to the second page. Do you see it repeats the finding at the top regarding soliciting input from distributors or associations representing distributors, that language we looked at?

MR. ACKERMAN: Your Honor, it's your discretion, but I'd note that the document is still on the screen as if it's been admitted. Now it's not.

THE COURT: It's been removed. Okay.

MR. SCHMIDT: It's gone.

BY MR. SCHMIDT:

Q. Do you see that finding we talked about?

MR. FARRELL: Objection, Your Honor. I don't know that he's identified that the witness has seen this document, let alone seen Page 2.

MR. SCHMIDT: I'm trying to move it in. Your Honor just said I could ask him -- use it as a basis to cross-examine and --

THE COURT: Well, yeah. You can use it as a basis to ask him questions --

MR. SCHMIDT: Okay.

BY MR. SCHMIDT:

Q. Do you see that finding --

THE COURT: -- for cross examination.

BY MR. SCHMIDT:

Q. Do you see that finding we've just discussed, sir?

A. On number 2?

Q. Yes, at the top of Page 2?

A. Okay.

Q. And then, if you look at the second paragraph, do you see it says the GAO survey was conducted in 2015, prior to new DEA leadership, including a new acting administrator and new management for the Diversion Control Division.

MR. FARRELL: Objection, Your Honor.

THE COURT: Mr. Farrell?

MR. FARRELL: He's simply reading it into the

record now rather than asking him questions.

THE COURT: Sustained.

MR. SCHMIDT: My question was simply going to be did he know about it and --

THE COURT: Well, you can ask him the question, but don't --

BY MR. SCHMIDT:

Q. Did you know about that finding?

A. No, I did not.

Q. Do you know about Congressional testimony Chuck Rosenberg gave before Congress after you left about the DEA being opaque when providing guidance to distributors?

A. I heard that before, yes.

Q. Are you aware that he said "I think we've been slow. I think we've been opaque. I think we haven't responded to them"?

A. I'm aware of that. I don't know where he got that information from. He never received a briefing from me before I left.

Q. Last topic, quotas. DEA sets quotas for controlled substances each year, correct?

A. Yes.

Q. But based on the estimated medical scientific research and industrial needs of the United States, correct?

A. That's correct.

Q. And they're designed to set an exact quantity that will meet the legitimate medical demands, yet won't be more than necessary that could be removed to the illicit marketplace, correct?

A. It's an estimate. It's not an exact quantity.

Q. But that's the estimate, correct?

A. That's the estimate.

Q. And distributors can only ship pills that manufacturers make within the quota, correct?

A. That's correct.

Q. You said you oversaw the aggregate production quota, the APQ, correct?

A. Yes. My staff did that.

Q. And I just want to go back to that earlier OIG Report.

A. Yes.

Q. DEF-WV-1597. And the reason I'm going to this is because it has a helpful chart that shows quota changes over time. It's at Page 19 of the document, please.

A. Yes.

Q. And are you generally familiar with the quota changes that happened at least on your watch between, according to this, 2015 and 2005? I probably did a terrible job at drawing those lines. I put my 2015 a little farther over. But are you generally familiar with those quota increases?

A. Yes.

Q. During your tenure?

A. Yes.

Q. And they had -- to be fair to you, they had started increasing before your tenure, going all the way back into the late 90s, correct?

A. Yes.

Q. And they continued to increase during your tenure, correct?

A. Uh-huh, yes.

Q. And am I correct in understanding from your testimony yesterday that you believe that those increases were driven by good faith prescribing practices?

A. I think my testimony was prescribing practices and then research and development, export, and the other things, yes.

Q. Okay. And the prescribing practices portion of that was driven by legitimate medical need, correct?

A. Well, legitimate medical need and then, of course, doctors that are prescribing illegally.

Q. Okay. You said yesterday you took diversion into account though in setting the quota, correct?

A. We looked at that over the years, yes.

Q. And you had the concern that if you arbitrarily cut the level of the quota, that could have negative consequences for real-life patients, correct?

A. Yes, that's correct.

Q. Now --

THE COURT: If you're at a stopping place, Mr. Schmidt, we need to take a break.

MR. SCHMIDT: Okay. Why don't we take a break, Your Honor.

THE COURT: Is this is a good place?

MR. SCHMIDT: Yes, sir.

THE COURT: All right. Let's be in recess for about ten minutes.

(Recess taken)

(Proceedings resumed at 3:40 p.m. as follows:)

THE COURT: Mr. Schmidt.

MR. SCHMIDT: Thank you.

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, I have one final topic that I hope is brief that I have to cover in light of some of the opinions you've given. You gave some pretty strong opinions about the distributors in this case. Correct? You offered -- let me re-ask. You offered some pretty strong views on the distributors in this case; correct?

A. I offered views on distributors, yes.

Q. You've also offered strong views in your work on doctors in terms of blaming doctors; correct?

A. I've discussed doctors and what their role is, yes.

Q. For example, just a few weeks ago you recorded on a

television showing saying the opioid crisis started with prescriptions, prescriptions and patient care, this idea that we weren't adequately treating pain. Correct?

A. Which show was that?

Q. It was the HBO show.

A. I don't have a transcript, but I seem to remember saying something about doctors during that time.

Q. Do you believe that the opioid crisis started with prescriptions?

A. I believe the opioid crisis -- the prescriptions had a lot to do with the opioid crisis, yes.

Q. Do you believe it started with prescriptions?

A. I would say that prescriptions -- yes, I'd say that.

MR. SINGER: Objection, move to strike, Your Honor. I think Mr. Schmidt, after objecting to expert opinions from this witness, is now seeking just that.

THE COURT: Well, I don't think that's an expert opinion. That's a lay opinion based on his experience, isn't it, Mr. Schmidt?

MR. SCHMIDT: I think so, Your Honor.

THE COURT: I'll overrule the objection.

BY MR. SCHMIDT:

Q. You've taken issue with manufacturers in your work; correct?

A. Yes.

Q. You've taken issue with chain pharmacies in your work; correct?

A. Yes.

Q. You blamed independent pharmacies; correct?

A. Yes.

Q. In terms of you, you had ultimate authority of the Office of Diversion Control for 10 years during the opioid crisis; correct?

A. Yes.

Q. There was an opioid crisis the entire time that you were the head of DEA's Office of Diversion Control; correct?

A. That's correct, yes.

Q. It worsened during your tenure; correct?

A. It, it did increase, yes.

Q. Including here in West Virginia; correct?

A. I -- yes.

Q. And you were the senior --

A. Across the country.

Q. Yes. You were the senior most law enforcement official at DEA responsible for pharmaceutical diversion; correct?

A. That's correct, yes.

Q. And despite the issue you've taken with others, am I right that you take no responsibility for the opioid crisis?

A. I don't take any responsibility for the opioid crisis, no.

Q. Zero percent?

A. Yes, zero percent.

Q. In fact, I've had the chance to ask you questions about your fulfillment of these responsibilities, and you've told me when it comes to registration, with the powers available to you, you believe you were perfect?

A. We did registration in line with what the law allowed us to do, yes.

Q. Registration of doctors and pharmacies, given the powers you had, did you execute those powers perfectly?

A. We executed them according to the law. So if we're dealing with the law, yes, we, we did it as far as the law would allow us to do.

Q. Given the powers you had to investigate doctors and pharmacies, you exercised those perfectly. True?

A. Yes, within the resources we had and within the law, we did, yes.

Q. Given the powers you had regarding quotas, you believe you executed those powers perfectly; correct?

A. Again, we were required to follow the statutes and the laws related to quota and we did so appropriately, yes.

Q. You believe you did so perfectly given the powers you had regarding quotas?

A. We did the best we could do within the confines of the law, yes.

Q. Let's cull up July -- all right. Nevermind. And you think you gave perfect guidance to distributors; correct?

A. We gave the distributors the guidance that we were able to give within the confines of the policies and procedures of both DEA and DOJ.

Q. And you wouldn't do anything differently in terms of how you approached the opioid crisis while you were at the DEA; correct?

A. I've thought about this because you asked that before.

Q. Do you remember how you answered it before?

A. I wasn't, I wasn't sure. I wasn't -- I don't remember how I answered it before, but I, I didn't have a lot of time to think about it.

Q. Okay. Would you do things differently? Just "yes" or "no"?

A. It's not a "yes" or "no" question.

Q. I'll move on then. You left the DEA in 2015; is that right?

A. Yes.

Q. And, in your words, you retired because they transferred you to another area of the DEA and you felt it was time to leave; correct?

A. Yes. They, they transferred me -- they basically said that I'll be in a position that will be named later so --

Q. You went from supervising 300 people to supervising no

people; correct?

A. That's correct.

Q. And that wasn't a change you wanted; correct?

A. I accept the fact that the acting administrator -- you serve at the will of the administrator. And the acting administrator wanted to make a change, so I accepted that fact.

Q. It wasn't a change you requested, was it?

A. It wasn't a change that I requested, no.

Q. And instead of agreeing to hold a position where you supervised no people, you chose to retire; correct?

A. I decided that there was uncertainty with what was going to happen. I could have been transferred. I didn't want my family to get transferred another time. So I decided to stay -- to retire, yes.

Q. At the time you retired, or prior to the time you retired, the Office of the Inspector General opened an investigation of you regarding serious misconduct with the House of Representatives; correct?

A. They opened an investigation of me because the House of Representatives -- two, two representatives claimed that I tried to intimidate them.

Q. And you left the DEA without getting a letter from the Office of Inspector General exonerating you; correct?

A. I never received a letter.

Q. Since you've left, you now get a government pension; correct?

A. I do have a government pension, yes.

Q. And your only other income comes from working with plaintiff lawyers; correct?

A. Yes.

Q. And I think you said the other day, or maybe yesterday, that you've received $860,000 for working with plaintiff lawyers in opioid litigation since you left the DEA; correct?

A. Yes, since 2017.

Q. And you testified that you weren't getting paid for your testimony here; correct?

A. Testimony or prep.

COURT REPORTER: I'm sorry?

THE WITNESS: Prep, testimony or preparation.

BY MR. SCHMIDT:

Q. But you have been paid money, a small portion of that $860,000 from one of the law firms in this case; correct?

A. Yes, a very small portion.

Q. Small portion being $7,000; correct?

A. Yes.

MR. SCHMIDT: That's all I have, Your Honor.

THE COURT: Any other cross of Mr. Rannazzisi?

MS. WICHT: Yes, Your Honor, there will be. Can I just have the Court's indulgence for a moment while we get set up here?

THE COURT: Yes.

MS. WICHT: Thank you.

CROSS EXAMINATION

BY MS. WICHT:

Q. Good afternoon, Mr. Rannazzisi.

A. Good afternoon.

Q. My name is Jennifer Wicht and I represent Cardinal Health. I am going to be doing my best to not duplicate any of the questions, or many of the questions you've already answered so far. And as a result, it may seem that I'm jumping around a little bit among topics. So I apologize for that and I hope you can follow me.

So I want to start, Mr. Rannazzisi, by following up on -- just a little bit on the questions that you addressed both with Ms. Singer and with Mr. Schmidt and you testified about pain clinics. Do you recall generally testifying about that topic?

A. Yes.

Q. Okay. And I, I believe the testimony that you've already given is that there are pain clinics that are legitimate -- engaged in the legitimate practice of medicine; correct?

A. That's correct.

Q. And there are also prescribers who specialize in the treatment of pain; correct?

A. That's correct.

Q. And the same thing that's true of pain clinics is true of prescribers who specialize in the practice of pain; that is, there are prescribers who specialize in the practice of pain who are engaged in the legitimate practice of medicine. Correct?

A. That's correct.

Q. So not -- just because a doctor is a pain specialist doesn't mean that they're prescribing in any sort of a rogue fashion; correct?

A. Could you repeat that, please?

Q. Sure. Just because a physician is a pain specialist, that doesn't mean that they're prescribing in any sort of a rogue fashion?

A. That's correct. In the alternative, a pain specialist can prescribe in a rogue fashion as well.

Q. But not all of them are?

A. That's correct, not all of them.

Q. Okay. I want to just go back for a moment to the definition of suspicious orders in the Code of Federal Regulations. And I think we have our own version of it that I'll put up on the screen which I think is slide 3, but

you've looked at it with both Ms. Singer and Mr. Schmidt.

I actually had the wrong slide. I apologize. Can we try 2? There we go.

And this -- you recognize that as the Code of Federal Regulations' definition of a suspicious order; correct?

A. Yes.

Q. And the Code of Federal Regulations is what provides the legal definition of a suspicious order; correct?

A. Yes.

Q. And that's DEA's official definition of a suspicious order as well; right?

A. The DEA follows the Code of Federal Regulations, yes.

Q. And there's no other definition that you're aware of of a suspicious order; correct?

A. Just the Code of Federal Regulations' definition.

Q. Now, the definition includes some terms we've already talked about; orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Correct? Those are the components of the definition of a suspicious order under the regs?

A. Yes.

Q. And the regs don't -- the regulations do not further define the term "unusual size;" correct?

A. That's correct.

Q. Nor do they offer a further definition of "unusual

frequency;" right?

A. That's correct.

Q. And they don't define what it means to deviate substantially from a normal pattern; correct?

A. That is correct.

Q. And the regulation doesn't quantify what the line is between usual and unusual; right?

A. That is correct also.

Q. And, now, when you were at DEA -- and I'll talk about your time between 2005 and 2015 that we've generally been focused on -- if a registrant asked you what a suspicious order was, you would tell them it's an order of unusual size, frequency, or substantially deviating from a normal ordering pattern; correct?

A. We would refer them to the regs. And if they had a specific question, then depending on who they were talking to, if it was liaison policy, I'm sure the liaison policy would have given them some type of guidance if it's specific to, specific set of facts.

Q. You would have referred the registrant to the definition in the, in the regulation; correct?

A. Unless they had some specific set of facts that they were looking for, yes.

Q. And if a registrant had a specific set of facts about an order, would the DEA tell them that's an order of unusual

size or pattern or frequency?

A. No. I'm talking about a specific set of facts as far as -- for instance, if they'd say, "What if I have a customer that's ordering an over-abundance of a certain type of drug?" And then I believe that they might say, "Well, what's the drug?" And they might say, "Well, we would consider this in the category of substantially deviating," say. So they might -- further explain. And then actually the letter, the December, 2007 letter further explained those as well.

Q. During your tenure, sir, isn't it correct that DEA took the position that it would not tell a registrant whether a particular order was a suspicious order under the definition of the regs?

A. That's correct. We would not be specific -- we would not tell a registrant, "This is, this is suspicious, don't ship it." We wouldn't say that.

Q. And it's true, is it not, that in your view there are lots of different ways that you could define unusual size; right?

A. Yes.

Q. It could mean unusual in comparison to that particular pharmacy's past ordering practices; right?

A. That's correct.

Q. It could mean unusual when compared to the ordering

practices of other pharmacies in the area; correct?
A. That's also correct.
Q. And there could be other factors that would bear on whether an order was of unusual size as well; correct?
A. Yes.
Q. And, now, the word "unusual" also applies to the consideration of order frequency under the regulations; correct?
A. Yes.
Q. And those various definitions or ways of determining whether an order is unusual are not spelled out in the regulations; correct?
A. No.
Q. And let me -- you, you testified about the possibility that if a registrant called, your staff might provide guidance or input to the registrants on a particular situation they had.

So let me just ask you this. You're not aware, are you, Mr. Rannazzisi, of any specific guidance that your staff offered to a registrant; correct?
A. No. However, that's -- the December letter provided a little more specific guidance on what an unusual -- what to look for on unusual size, frequency, deviating substantially from the normal ordering pattern.
Q. Since you mentioned the December of 2007 letter, let me

just ask -- that was the last guidance letter that your office sent to registrants, correct, during your tenure at DEA?

A. Yes.

Q. There were no additional letters sent after that providing guidance?

A. I don't recall any additional letters.

Q. You've testified, Mr. Rannazzisi, on direct examination about -- that distributors in their Suspicious Order Monitoring Systems could use dispensing data from their pharmacy customers. Do you recall that?

A. Yes.

Q. And, and that's a subject that you've offered opinions about in a, in a different opioid case, correct, dispensing data and suspicious order monitoring?

A. I don't recall if I discussed that in the MDL deposition or another case. I know I discussed it. I just don't remember which case I discussed it in.

Q. Okay. No problem. And I want to be -- I really was only saying that to say that I want to be clear. I'm not asking for any opinions that you may have offered somewhere else.

A. Okay.

Q. What I want to ask you is while you were at the DEA, Mr. Rannazzisi, you never told distributors that they must

or should be collecting dispensing data from their pharmacy customers and incorporating it into their Suspicious Order Monitoring Systems; correct?

A. I never told anybody --

Q. And --

A. -- that.

Q. And --

A. But that doesn't -- you know, that doesn't include the staff. That was one of the things that I'm sure they discussed with the distributors.

Q. You're not aware of any instance in which staff discussed that with any distributor; correct?

A. I can't give you a specific instance, but I knew staff knew the dispensing data was important.

Q. And while you were at the DEA, DEA, to your knowledge, never issued any written guidance telling distributors that they must or should collect dispensing data from customers; correct?

A. I never said they should collect. I've said during due diligence they should review it if they can't resolve the reason for the, for the anomalies and ordering patterns. So we suggest it's part of the due diligence process.

Q. Well, let's be clear, though. You've testified that you never -- you don't recall ever saying that to any distributor though; correct?

A. I never said it.

Q. And you're not aware of staff saying that to any distributor; correct?

A. I can't give you an instance where staff has said that.

Q. I'm going to ask you some questions specific to Cardinal Health, Mr. Rannazzisi.

Yesterday Ms. Singer refreshed your recollection with an affidavit that you signed in the Cardinal Health, 2012 Cardinal Health action. Do you remember that?

A. Yes. It was a declaration in lieu of testimony.

Q. Okay. And after she showed you that declaration, you testified that DEA conducted an audit of Cardinal Health's Peabody, Massachusetts distribution center; and that during that audit, Cardinal Health was given guidance by DEA on due diligence for chain drug stores. Do you recall that?

A. Yes.

Q. I just have a few questions about that, Mr. Rannazzisi. To be clear, you did not conduct that audit of Cardinal Health's Peabody distribution center; correct?

A. No. I believe it was Inspector Mike Arpaio that was the lead auditor in that.

Q. And he conducted that audit --

A. Yes.

Q. -- of Cardinal Health? So everything that you know about that meeting between DEA and Cardinal Health at that

audit you learned from Mr. Arpaio; correct?
A. Yes.
Q. And that includes anything that Mr. Arpaio might have said to Cardinal Health, correct?
A. Yes.
Q. And anything that Cardinal Health employees said to Mr. Arpaio; correct?
A. That's correct.
Q. You were shown a copy yesterday of a memo memorializing the internet pharmacy briefing that certain DEA officials conducted with Cardinal Health. Do you recall that?
A. Yes.
Q. And we can pull that up. It's P-9114.
Do you have that in front of you still, Mr. Rannazzisi?
A. I'm not even looking for it. It's on the screen.
Q. Okay. It's on the screen. And the subject line of that memo states "Meeting with Cardinal Health, Inc., Concerning Internet Pharmacies." Correct?
A. That's correct.
Q. And you testified that you didn't attend this meeting; right?
A. I did not attend this meeting.
Q. And the memo was prepared by Mr. Michael Mapes; correct?
A. That's correct.

Q. And he did attend the meeting; correct?

A. I believe he was the principal briefer, yes.

Q. Along with Mr. Kyle Wright from the DEA?

A. I can't see who's --

Q. Yeah. If you look at the --

A. That's what I'm looking at now.

Q. You know what --

A. Yeah. I don't believe Kyle Wright's in here.

Q. Okay. Fair enough. And the, the, the way that you learned about the meeting, Mr. Rannazzisi, was from this memo and a briefing; correct?

A. This memo came after I was briefed on the meeting.

Q. And --

A. I was briefed on the meeting after the meeting either that day or the next day. And then I would get the memo following.

Q. And the memo that the DEA staff prepared after the meetings were to inform you about what was said at the meeting and what was talked about; correct?

A. Actually, it was to memorialize the meeting.

Q. To memorialize the meeting?

A. Yes.

Q. Okay. And you wanted those memos prepared; correct?

A. Those memos would be prepared for any meetings we had, so, yes.

Q. And I'm sure you expected your staff to make sure that the memos were complete, didn't you?

A. Yes.

Q. And, of course, the memos needed to be accurate; correct?

A. Yes.

Q. And these were important meetings and it was important to you to document what had been said to the distributors at the meeting; correct?

A. Yes.

Q. And if you thought that the staff would have conducted the meeting and you were missing some information that you thought should have been included, you probably would have added it in or asked them to include it; correct?

A. If there was something missing that I knew was missing, I would ask them. But since I wasn't at the meeting, I relied on them to accurately report and memorialize the meeting.

Q. So if you take a look at this memo, Mr. Rannazzisi, and it's just the one page that you see on the screen there, the memo doesn't contain any discussion of ingredient limit reports, does it?

A. No, it doesn't.

Q. It doesn't contain any discussion of excessive purchase reports, does it?

A. No, it doesn't.
Q. It doesn't contain any discussion of after-the-fact reports of shipments; correct?
A. No, the memo doesn't contain any of that.
Q. The memo doesn't reflect any discussion of -- the memo doesn't say that Cardinal Health was told that when they were recording a suspicious order, they were required to say why the order was suspicious; right?
A. No, that's not in there either.
Q. And the memo doesn't say that Cardinal Health was told that when they were reporting a suspicious order, they should provide information about the pharmacy; correct?
A. No, that's not in there. But I do believe that some of that is -- would be attached in the PowerPoint presentation that was given.
Q. Well, the PowerPoint presentation -- if you have the exhibit in front of you -- it should be there behind it, Mr. Rannazzisi. So I'll invite you to flip through it and let me know if you see something in the PowerPoint presentation that said when a suspicious order is reported, the distributor is required to say why the order is suspicious.
A. Well, this was -- I don't know if that was in the PowerPoint or not, but some of the other things you asked me --
Q. Well --

A. -- were definitely in the PowerPoint.

Q. Well, that's what I'm asking you about now. So you're saying -- your answer is that's not in the PowerPoint?

A. I don't have the PowerPoint in front of me, but I don't, I don't remember it being -- I don't recall it being in the PowerPoint. But I have a lot of paper in front of me so -- you don't happen to have it, do you?

Q. I believe I do. I can hand you another copy. I'm happy to. It's P-9114. Maybe I don't have it.

MS. WICHT: I'm sorry, Your Honor. I'll check. May I approach, Your Honor?

THE COURT: Yes.

BY MS. WICHT:

Q. And the question that I've asked you, sir, is whether there's anywhere in that memo or PowerPoint presentation that indicates what information Cardinal Health was required to submit to DEA in a suspicious order report.

A. I don't, I don't see it in the PowerPoint.

Q. Now, the, the memo, Mr. Rannazzisi, also doesn't say anything about any obligation to document due diligence; correct?

A. No, it does not.

Q. Now, are you aware that Kyle Wright testified that he did not tell distributors in these internet pharmacy

briefings that there was an obligation to document due diligence?

A. No, I was not aware of that. I don't know what Kyle Wright's testimony is.

Q. I'm sorry. The last part?

A. I don't know what Kyle Wright's testimony is.

Q. But Kyle Wright --

A. I don't even know if Kyle Wright was at this meeting.

Q. But Kyle Wright in general was one of the presenters at the distributor initiative meetings; correct?

A. Yeah. He was one of several, several people who attended these meetings.

Q. And you were not; correct?

A. No, I was not.

Q. And are you aware that Mr. Mapes testified that if there had been anything else discussed in the meeting with Cardinal Health, he would have included it in his cover memo?

A. Again, I didn't see Mr. Mapes' testimony, so I don't know.

Q. But that would be consistent with your expectations for what was included in the memo; correct?

A. I would expect that Mr. Mapes would do a complete memo including everything else in -- that happened during the meeting.

Q. Mr. Rannazzisi, do you know which Cardinal Health distribution center shipped medications to Cabell/Huntington, West Virginia.

A. No, I don't.

Q. Are you aware that Cardinal Health has a distribution center in Wheeling, West Virginia?

A. No, I'm not aware of that.

Q. In your entire --

MR. ACKERMAN: One minute. I think I know where we're going. I'm going to preserve our scope objection with respect to questions regarding West Virginia because Mr. Rannazzisi was not questioned regarding West Virginia in his MDL deposition.

THE COURT: Okay.

MR. ACKERMAN: And that will be a standing objection. I don't want to interrupt.

BY MS. WICHT:

Q. Now, Mr. Rannazzisi, during your entire tenure at DEA, DEA never issued an Order to Show Cause against Cardinal Health's Wheeling, West Virginia distribution center; correct?

A. I, I don't know, but during my -- I don't know if they ever received one or not. I think I would remember that, but I'm not sure.

Q. During the time that you were at the Office of

Diversion Control from 2005 to 2015, it's fair to say you would remember if you had issued an Order to Show Cause against Cardinal Health's Wheeling, West Virginia distribution center?

A. I think I would remember, yes.

Q. And you don't recall that; correct?

A. I don't recall that.

Q. And during the time that you were in the Office of Diversion Control at DEA, DEA never issued an Immediate Suspension Order against Cardinal Health's Wheeling, West Virginia distribution center; correct?

A. I -- if they didn't get an Order to Show Cause served on them, they wouldn't have an ISO.

Q. You discussed with Ms. Singer yesterday an enforcement action that was taken against other Cardinal Health distribution centers in late 2007. Do you recall that?

A. Yes.

Q. And that -- those enforcement actions issued against distribution centers other than Wheeling, West Virginia concerned distributions to what DEA contended were internet pharmacies; is that right?

A. Yes. I'd have to go back and look at the Order to Show Cause but, yes, I believe that's correct.

Q. All right. Now, at the time that DEA took action against Cardinal Health in 2007, your office had possession

of Cardinal Health's ARCOS data going back years before 2007; correct?

A. I would hope so. Cardinal Health was required under the Act to provide that ARCOS data.

Q. And Cardinal Health did provide that ARCOS data; correct?

A. Yes, I guess, yes.

Q. You don't have any recollection --

A. I don't have any recollection that they didn't, but they're required to under the Act under 827.

Q. And DEA used that ARCOS data to identify shipments that DEA alleged were suspicious in the 2007 Orders to Show Cause and ISOs; correct?

A. Retrospectively, yes, because they were not -- we didn't have the suspicious orders.

Q. And enforcement action against Cardinal Health's Lakeland, Florida distribution center in 2012 raised allegations about Cardinal Health's distributions to four specific pharmacies in Florida. Do you recall that?

A. I, I think I said I don't have the document, but if you want me to look or if you have the Order to Show Cause document or --

Q. That's okay. I'll move on from the specifics if you don't recall and I'll just ask you this. At the time that DEA took action against Cardinal Health in 2012, again your

office had possession of Cardinal Health's ARCOS data going back years before that; correct?

A. Yes, we did. But, again, ARCOS, ARCOS data could only be looked at retrospectively, months after transactions occurred.

Q. And you used that ARCOS data to identify shipments that DEA alleged were suspicious in the context of the Lakeland, Florida Immediate Suspension Order; correct?

A. Yes, that is correct.

Q. And that ARCOS data that you used in 2007 and 2012 to form the basis of the allegations in the enforcement action also reflected every shipment of opioids by Cardinal Health to every pharmacy in West Virginia; correct?

A. Yes, it should.

Q. And, obviously, that would include every pharmacy in Cabell/Huntington; correct?

A. Again, it should, yes.

Q. Now, from the -- from 2012 until the time you left DEA in 2015, DEA continued to receive ARCOS data reflecting every shipment of every opioid by Cardinal Health to every pharmacy in Cabell/Huntington; correct?

A. Again, according to 827, that's a requirement, so, yes.

Q. And you're not aware of Cardinal Health ever failing to fulfill that requirement; correct?

A. I'm not aware of that.

Q. Now, during your tenure with the Office of Diversion Control from July, 2005 to October of 2015, you never instituted any enforcement proceedings against Cardinal Health based on any shipment made to Cabell/Huntington, West Virginia; correct?

A. I don't believe so.

Q. In your work at DEA, you never conducted any inspection of Cardinal Health's Suspicious Order Monitoring System; correct?

A. Me personally?

Q. You personally.

A. No.

Q. And you're familiar with a DEA employee name Kyle Wright; correct? You've mentioned him a few times already.

A. Yes.

Q. He -- Mr. Wright reported to you?

A. He reported to his section chief who ultimately reported to me, yes.

Q. Are you aware that Mr. Wright regularly communicated with Cardinal Health between 2005 and 2007 about Cardinal Health's efforts to address DEA's concerns about internet pharmacies?

A. Well, he was in a section that would talk to not just Cardinal Health, but other types of registrants.

Q. So you, you would expect him to have been talking to

Cardinal Health on that subject in that time frame; right?

A. I expected him to talk to a number of registrants, yes.

Q. Including Cardinal Health?

A. Yes.

Q. And are you aware that on April 26th, 2007, Kyle Wright spoke with two of the Cardinal Health employees in charge of anti-diversion and told them that he thought they were, quote, doing the right things and heading in the right direction?

A. I don't recall that specific -- I don't recall that, no. Do you have the document or --

Q. I was just asking if you were aware of it, sir.

A. No, I don't believe I was aware of that.

Q. Now, you mentioned on your direct examination with Ms. Singer someone named Barbara Boockholdt --

A. Boockholdt.

Q. I'm sorry -- who worked with you at DEA?

A. Yes.

Q. And she was the chief of the regulatory section at DEA headquarters; is that correct?

A. Chief regulatory investigations, yes.

Q. And are you -- you're aware, are you not, that in 2009 DEA officials conducted a week-long visit at Cardinal Health's headquarters in Ohio meeting with Mr. Michael Mone and others to review Cardinal Health's improvements to its

Suspicious Order Monitoring System?

A. I recall that there was a team that went to Cardinal. I don't recall who exactly was on that team or when it happened. But, yeah, I recall there was a meeting.

Q. And are you aware that Ms. Barbara Boockholdt attended that meeting from DEA headquarters?

A. If it was a regulatory meeting, there's a good possibility that she would have attended that meeting.

Q. But you did not attend the meeting; correct?

A. I did not attend that meeting.

Q. So you don't know what DEA said to Cardinal Health about Cardinal Health's Suspicious Order Monitoring System in that meeting; correct?

A. I do not.

Q. After you left DEA, are you aware of the fact that there were meetings between Mr. Todd Cameron, the head of Anti-Diversion at Cardinal Health, and officials at DEA headquarters to talk about Cardinal Health's Suspicious Order Monitoring System?

A. It would be after I left, so, no.

Q. You're not aware of those -- how many meetings occurred?

A. No.

Q. Obviously, you didn't attend?

A. Not after I left, no.

Q. Before you left DEA, had you invited Mr. Cameron in to, to DEA to discuss Cardinal Health's system?

A. I never invited Todd Cameron -- is it Todd Cameron? Yeah. No.

Q. So do you have -- so you never received -- it's fair to say you never received any information or briefing on Cardinal Health's Suspicious Order Monitoring System post 2012; correct?

A. The last briefing I received was before I was going to testify in the TRO hearing in Washington, D.C.

Q. And that would have been in 2012 sometime?

A. That would have been, yeah, probably February -- February of 2012 sometime, February or March of 2012.

Q. And after that point in time, after that briefing, you have no knowledge about what Cardinal Health's Suspicious Order Monitoring System, how it operated; correct?

A. After that time, no.

MS. WICHT: May I have a moment to confer, Your Honor?

THE COURT: Yes.

(Pause)

MS. WICHT: That's all I have. Thank you very much.

MR. NICHOLAS: Yes, Your Honor, I do have some questions.

THE COURT: Go ahead.

CROSS EXAMINATION

BY MR. NICHOLAS:

Q. Good afternoon, Mr. Rannazzisi. How are you?

A. Fine.

Q. You and I, we met once before on Zoom?

A. Yes, we did.

Q. Do you remember that?

A. I do remember that.

Q. Good. It's not the most satisfactory way to meet people but, you know, --

A. It's nice meeting you in person.

Q. Same here.

A. Of course under these circumstances.

Q. Yeah, right. And I will say as we get set up technically that I have a tremendous misfortune of being -- of having my examination begin at 4:25 in the afternoon on a long Wednesday, so I apologize for that.

I want to apologize to the Court in advance in case I can't finish today. It's just one of those things. I'm not going to be that long, but I'm not sure I can get done by 5:00. So please forgive me in advance.

A. Actually, this was the same circumstance we were under the last time.

Q. You know, you're absolutely right. You have a good

memory.

Okay. I guess I'll just begin by asking you this question. You have testified both yesterday and today that at least during your time at, you know, in your supervisory position between 2005 and 2015, the DEA did not approve Suspicious Order Monitoring Systems that were developed by distributors; is that correct?

A. That is correct.

Q. Okay. And is it your testimony that the DEA did not approve such systems before your tenure?

A. DEA -- the policy that was in place before my tenure was the same policy -- I'm testifying from 2005 to 2015. But I was told that that was the policy when I got to the Office of Diversion Control in -- actually, in 2004 when I originally got to the Office of Diversion Control, that was the policy.

Q. You say you were told. Was there a written policy that so stated or are you just telling us what your recollection is of what you were told?

A. I'm telling you my recollection. I had briefings on any number of topics and I was -- when we came into that, that distributor initiative briefing when I started asking questions about suspicious order monitoring, they said that the Suspicious Order Monitoring Systems were up to the companies. And we would not intervene, or we would not tell

them how to file them and they directed me to 1301.74(b). Actually, that was the first time I actually looked at 1301.74(b).

Q. Were you aware that the DEA had approved a Suspicious Order Monitoring System developed by AmerisourceBergen between 1996 and 1998?

A. No.

Q. Okay.

MR. NICHOLAS: Ritchie, can we cull up AM-WV-0258? And let's hand it out.

May I approach, Your Honor?

THE COURT: Yes.

BY MR. NICHOLAS:

Q. Do you recognize this document?

A. Yes, I've seen this document before.

Q. Is it an approval from the DEA of AmerisourceBergen's Suspicious Order Monitoring System as of 1998?

A. I believe there's a request letter that goes along with this. So this letter says, "We're granting approval to your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals as required by federal regulations."

But I believe there's another letter that discusses what the approval actually -- what the request for approval

is.

Q. Well, there's a series of letters and we will go through them. But right now I'm asking you to look at this letter and tell me whether it is an approval of AmerisourceBergen's newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals as required by federal regulation.

A. That's what this letter says, yes. But --

Q. Okay.

A. -- I'd like to see the request letter that's attached to it.

Q. We will get to that. We will get to the correspondence. But looking at this letter -- well, let's back up. The letter is written to Chris Zimmerman, the Director of Regulatory Compliance and Security Services for Bergen Brunswig Corporation. Do you see that?

A. Yes.

Q. Okay. And Bergen Brunswig is the predecessor of AmerisourceBergen; correct?

A. Yes.

Q. Okay. And the letter is written on U.S. Department of Justice letterhead; correct?

A. That's correct.

Q. And it says "Drug Enforcement Administration" under that; right?

A. Yes.

Q. And it's dated July 23rd, 1998; correct?

A. Yes.

Q. Okay. Now, it's signed by Patricia M. Good. Do you see that?

A. Yes.

Q. And she was the Chief Liaison and Policy Section, Office of Diversion Control. Do you see that?

A. Yes.

Q. Now, I also want to ask you about the cc's because this was cc'd to DPMs. Let's start with DPMs.

A. Yes.

Q. Does that stand for Diversion Program Managers?

A. Yes.

Q. Okay. How many Diversion Program Managers were there in 1998?

A. I, I don't know how many there were in 1998.

Q. Can you give me a ball -- can you ballpark it?

A. Well, there's 21 field divisions. I'd guess there would be about half, so probably, maybe 10 or 11.

Q. So this was cc'd to 10 or 11 Diversion Program, Diversion Program Managers; correct?

A. That's correct.

Q. All right. What does OD/D stand for? Is it Office of Diversion Control?

A. Yeah. I believe -- and, again, this is way before my time. But I believe that was designated for the Office of the Deputy Director.

Q. Okay. It was also cc'd to ODX. What's ODX?

A. That would be the executive assistant to the deputy assistant administrator.

Q. Okay. And if you see at the bottom it says "Subject: Approve Suspicious Order Monitoring System." Do you see that?

A. Yes, I see that.

Q. Is there anything about this letter that would lead anyone to a conclusion other than that as of July 23rd, 1998, the DEA had approved Bergen Brunswig's newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals as required by federal regulation?

THE COURT: Mr. Ackerman.

MR. ACKERMAN: Objection, speculation, foundation, calling for an opinion.

THE COURT: Overruled. The question was: Is there anything about this letter that would -- I think he can answer that.

THE WITNESS: When I look at a letter like this, I would like to review what the actual request was before because I know it says "Subject: Approve Suspicious Order

Monitoring System." But, quite frankly, I don't -- I've never seen this, this -- the bottom of the thing with the cc's, usually that's on a separate, a separate paper separated from the actual correspondence.

So I'm just -- I'm not saying this is wrong, but I'm just -- I -- before I comment on it, I'd like to see what you're actually request, requesting from DEA before you get, you know, my response because I don't know. I mean, I wasn't there in 1998 and I don't know exactly what you requested from DEA.

BY MR. NICHOLAS:

Q. All right. Well, just so, just so there's no uncertainty on the record, this document and this version of this document was produced by the DEA from their files.

A. Okay.

Q. So if you're, if you're suggesting there was something improper about it --

A. Absolutely -- I'm not suggesting anything. I just -- generally, when this cc is written like this, it's on a separate page. That's all I'm saying. And that's why I just didn't -- I just -- I've never seen it set up like this. But, then again, this was 1998.

Q. It was 1998.

A. So -- but, again, I just can't give you an answer

without seeing what the actual request was.

Q. Well, on its face, it's an approval; correct?

A. On its face, it looks like an approval.

Q. And when it was cc'd --

THE COURT: Mr. Farrell.

MR. FARRELL: Objection. We're going to repeat the foundation objection. This witness has said he wasn't there. And to be fair to both sides, this document was discussed at length in the Prevoznik deposition through a 30(b)(6) witness proffered by the DEA.

MR. NICHOLAS: I don't know what relevance that has to this.

THE COURT: Well, I think you need to move on. I think you're kind of beating this into the ground, Mr. Nicholas.

MR. NICHOLAS: Okay. I certainly don't want to beat anything into the ground.

BY MR. NICHOLAS:

Q. So why don't we go to the correspondence that preceded this approval between -- that occurred between 1996 and 1998. And let's start with -- let's go to exhibit AM-WV-00781, please.

And what I'm handing out is another, is another copy of the approval letter. But attached to this exhibit is a series of correspondence that I will ask you about. And

this is the correspondence that you were asking me about, Mr. Rannazzisi.

MR. NICHOLAS: May I approach, Your Honor?

THE COURT: Yes.

THE WITNESS: Thank you very much.

MR. FARRELL: Without belaboring the point, again, objection to the foundation with this witness with this series of documents. The record is going to have much more detail from other witnesses with direct knowledge including the DEA.

THE COURT: Well, I think this is cross-examination and I think Mr. Nicholas can use this as a basis to conduct his cross to a certain extent.

So go ahead, Mr. Nicholas. I overrule the objection.

MR. NICHOLAS: Thank you, Your Honor.

BY MR. NICHOLAS:

Q. Let's start with, let's start with -- first of all, just for the record, this is -- this document is already admitted in evidence, as was the prior document.

So moving on from there, if you will turn to Page 00009 which is the September 30th, 1996, letter to Mr. Thomas Gitchel. We can start with that. Tell me when you're there.

A. To Thomas Gitchel?

Q. Yes.

A. December 30th did you say?

Q. September 30th.

A. Okay. I got it.

Q. And if you look at the first -- well, this letter is dated September 30th. It's to Mr. Thomas Gitchel who as of that date was the Chief Liaison and Policy Section, Drug Enforcement Administration, United States Department of Justice. So he was Patricia Good's predecessor; correct?

A. That is correct.

Q. Okay. And the letter was sent by Chris Zimmerman from AmerisourceBergen; correct?

A. Yes.

Q. And Chris Zimmerman was the manager of corporate security -- I'm sorry -- for Bergen Brunswig at that time; correct?

A. Yes.

Q. And Mr. Zimmerman begins his letter by saying, "The purpose of this letter is to introduce the Drug Enforcement Administration, DEA, to an innovative new system under development by Bergen Brunswig Drug Corporation, BBDC, to monitor and report suspicious orders of controlled substances which fit the suspicious order criteria outlined in 21, C.F.R., Section 1301.74(b)."

Do you see that?

A. Yes.

Q. So this was AmerisourceBergen -- this was Bergen Brunswig's initiative. This was not initiated by the DEA. Right?

A. It appears that way, yes.

Q. And the next sentence that begins the next paragraph says, "By way of background, as you know, BBDC participated in the development of a model excessive purchase report now in use by many distributor registrants."

Do you see that?

A. Yes.

Q. Okay. And if you go to the -- if you go to the last sentence of the paragraph, it says, "The report is produced in hard copy form monthly and is sent via certified mail to each DEA field office having responsibility for the reporting BBDC locations."

Do you see that?

A. Yes.

Q. Now, you had spoken in your direct examination about the fact -- and you kind of -- you were describing it as something you were unhappy with, about the fact that these reports only came monthly to you. Do you recall that testimony, that they didn't come in real-time?

A. Well, they weren't suspicious order reports. They were excessive purchase reports.

Q. Well, we'll get to that. That's, that's your view. I

understand that. But you also were saying that the excessive -- even if you call them excessive purchase reports, they weren't coming timely. They were coming only monthly. Do you recall that?

MR. ACKERMAN: Objection. I think that misstates his testimony.

THE WITNESS: I think what I said was --

THE COURT: Just a minute.

THE WITNESS: I'm sorry, Your Honor. I'm sorry.

THE COURT: I'm not sure -- overruled. Go ahead.

THE WITNESS: Yeah. I think what I said was these excessive purchase reports that came monthly are not suspicious order reports and they really have little value. That's what I said. I'm pretty sure I said that.

BY MR. NICHOLAS:

Q. If you go to the next paragraph, Mr. Zimmerman writes to Mr. Gitchel. "While feedback from different DEA users over the years has generally confirmed our belief that this report, standing alone, is a useful law enforcement tool, BBDC's suspicious order compliance program also involves the telephonic reporting of customer orders to DEA. In an average year, BBDC logs over 12,000 telephone calls to DEA field offices nationwide." And then it goes on.

Do you see that?

A. Yes.

Q. Okay. And if you turn to the next page, Mr. Rannazzisi, and go to the middle of the page, there's a paragraph that begins "against." And it says, "Against this backdrop, BBDC set to work on the development of a suspicious order reporting program that would provide better quality information to DEA in a more efficient manner."

Do you see that?

A. Yes.

Q. So Bergen Brunswig was -- wanted to, wanted to develop a suspicious order reporting program that would provide better information to the DEA; correct?

MR. FARRELL: Objection, foundation, speculation.

THE COURT: Well, the letter itself speaks to that point, doesn't it, Mr. Nicholas?

MR. NICHOLAS: It does. I'm really responding to the fact that Mr. Rannazzisi in his direct testimony has suggested time and time again that the distributors did not do anything to provide information that was useful to the DEA. This goes square dead on directly to that, or I feel I have to at least show the witness.

MR. ACKERMAN: The concern we have, Your Honor, --

THE COURT: Well, this is cross-examination. I think this is proper. And for the reasons Mr. Nicholas just said, I'll allow it.

BY MR. NICHOLAS:

Q. Now, Mr. Rannazzisi, I, I'm mindful of what the Judge just said which is that the letter largely speaks for itself, and it does. But -- so if you look at the next paragraph, I will, I will spare everyone in the courtroom my reading of the paragraph.

But if you look at it, you can see -- tell me if you agree that, that Bergen Brunswig is proposing, you know, to provide substantive information that it believes will be more useful to the DEA than it has been provided previously.

And it makes reference to an average of the customer's prior four months of orders, customers whose orders exceed by a specific percentage their prior four-month average order history would be printed on a summary report.

It says at the end of the paragraph -- here I am reading it -- the summary report would show the customer name, address, DEA number, item description, NDC number, order date, active ingredient volume ordered, active ingredient shipped, and customer allowance.

So AmerisourceBergen -- so Bergen Brunswig is proposing to create a program that would provide all of that information to the DEA. Correct?

A. That's what the letter says, yes.

Q. Okay. And the letter also, also talks about the manner of transmission and the timing of transmission on the last

page where it says, "Our intent is to receive DEA's permission to replace our current manner of daily suspicious order reporting, e.g. U.S. mail and telephone calls, with this daily electronic facsimile report."

And then it says, "We would like to have DEA input on the final product because DEA will be the primary users. Our suggestion would be to coordinate with one of your field offices, perhaps the Los Angeles office, to meet with our project development team."

Do you see that?

A. Yes.

Q. And it proposes beta testing to be done in connection with the Los Angeles office, the DEA's Los Angeles office; correct?

A. Yes.

Q. Okay. So that's, that's the opening -- that's the first thing that was written on this subject and it was from Mr. Zimmerman to Mr. Gitchel.

Now, let's turn to, let's turn to Mr. Gitchel's response which is dated October 29th, 1996. It's the next letter in the chain. And it's written to Mr. Chris Zimmerman and it's signed by Thomas Gitchel of the DEA. And it refers to Mr. Zimmerman's letter to him.

And, Ritchie, can you just highlight the first sentence of the second paragraph, please? Can you pull that out?

Now, it begins, "We have reviewed your proposal."

A. Yeah.

Q. The first sentence: "We have reviewed your proposal and feel it to be a viable alternative to the current system."

Do you see that?

A. Yes.

Q. All right. So let's go down to the next paragraph which says, "We note that," and just pull the whole paragraph out.

And you can see here by this paragraph that Mr. Gitchel is engaging in the substance of the proposal; correct?

A. Well, the original request, the original request is to receive permission to replace current matter of daily suspicious reporting via U.S. mail or telephone calls with an electronic facsimile report. That's the request that was in this original email.

Q. Well, I'm not going to argue with you about what the original letter says and doesn't say, other than to remind you, Mr. Rannazzisi, that there was an extensive description of the kind of substantive information that Bergen Brunswig proposed to provide to the DEA. You recall that; right?

A. Well, it was laid out. But the only request that's in that email, or in that letter is a facsimile -- use of facsimile rather than telephone call or mail. And, and that

is the type of request that would, actually can be approved because it's just a change of reporting.

Q. Well, --

A. So --

Q. So your testimony is that over this two-year period of back and forth --

A. Uh-huh.

Q. -- between Bergen Brunswig and the DEA, the beta testing, the substantive discussions, the testing at various sites, that all of that only had to do with whether information would be faxed as opposed to mailed. Is that your testimony?

MR. FARRELL: Objection, Your Honor. Again, foundation. He wasn't there. He doesn't have direct knowledge. And there's extensive testimony of people with knowledge other places in the record.

THE COURT: Well, he can ask him about it. And if he doesn't know anything about it, he can say he doesn't know anything about it.

Go ahead, Mr. Nicholas.

BY MR. NICHOLAS:

Q. Do you know anything about it?

A. I was not there during this time period. But I can only go with the letters you gave me. And these letters -- this first one is a request for a change in the way that the

transmission of the suspicious order to the DEA offices.

And, yes, they would have to beta test that and it would go to multiple offices. And it takes time to beta test it. So I'm just saying that's what it says. I was not in headquarters at the time and I can't tell you exactly what they were doing.

MR. NICHOLAS: Ritchie, can we go back to the first exhibit that we looked at, AM-WV-02658.

BY MR. NICHOLAS:

Q. The first sentence says, "This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders."

Do you see that?

A. Yes, I do.

Q. So it uses the word "identify." It separates it with an "and." And then it says "and report." Do you see that?

A. Yes.

Q. Okay.

A. You know, just if I may, you have two of the exact same letter and these letters are totally different, even though they're exactly the same.

One is -- it looks like -- it looks like they're the same dates. They're the same "to" and "from." They're the same content. But it looks like they're totally different.

One's got the chopped sheet on the bottom. One doesn't have a chop sheet. One has Patricia Good's name on the top -- on the bottom and the other one has it underneath the "sincerely." These are the same letters, the same exact letters but two different copies.

Q. What are you suggesting?

A. Well, I -- because this one doesn't have this underneath -- I'm not suggesting anything. They're the exact same letters.

Q. Yeah.

A. So you're asking me to testify about something I -- I wasn't in headquarters at the time, but I've been in headquarters long enough to see differences in the exact same memo. And I don't -- it looks like they're two different memos for the exact same thing on the same date.

Q. Are you suggesting anything improper?

A. I'm not suggesting anything --

THE COURT: He's saying he doesn't know anything about them.

MR. NICHOLAS: Okay. That's fine.

BY MR. NICHOLAS:

Q. Let me ask you this, Mr. Rannazzisi.

Did you ever come to understand when you took your -- when you, when you became -- when you took over Diversion Control in 2005, were you made aware of the fact that this

approval was sitting out there that had been issued to Bergen Brunswig in 1998?

A. No, I was not.

Q. No one ever told you about it?

A. No. When I got to headquarters, they told me -- what I testified to was we don't approve Suspicious Order Monitoring Systems. That's what I was briefed on.

When we went into the distributor initiative -- the distributor initiative briefings, I understood that was part of the distributor initiative briefings, and we talked about that. It was in the letters. It was -- I mean, that's -- I can only go on my briefings.

I wasn't there in 1998. I don't know what they did in 1998. But when I was there, I was briefed by very competent staff who knew exactly what they were doing. And I was briefed on Suspicious Order Monitoring Systems. That's how I could go in and, and evaluate what they were doing to make a determination how they were doing it and if they're doing it appropriately.

Q. Did you ever talk to Patricia Good about this approval letter?

A. No.

Q. Did you ever talk to Thomas Gitchel about this approval letter?

A. Thomas Gitchel was retired when I got there, and Pat

Good was about ready to retire when I got there.

Q. Did you ever talk to Mr. Zimmerman about the approval letter?

A. No, I did not. Again, I want to tell you I'm not, I'm not accusing you or anything. But I, I'm trained when I look at documents like this, especially DEA documents, we're trained to look at them to ensure. So I don't know why there's two different ones, but I'm not accusing you of anything. I wouldn't expect that you would do anything like that.

Q. No, I --

A. I'm just saying they're the same documents but they're two different -- it's the same document, just two different set-ups.

Q. All right. I understand. I appreciate that.

Let's go to P-000032, 032.

MR. NICHOLAS: And, Ritchie, if we could go to Page 3 of that document and highlight the last sentence of the -- the last sentence of the second paragraph which begins with the word "past communications."

BY MR. NICHOLAS:

Q. Now, this is your December 27th, 2007, letter to all the manufacturers and distributors; correct?

A. Yes, sir.

Q. And it wasn't directed to -- it wasn't a letter

specific to anyone. It was just a general letter to the industry. Right?

A. Yes, sir.

Q. Okay. And this sentence says, "Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."

Do you see that?

A. Yes.

Q. Okay. Prior to and other than this statement by you in this letter, are you aware of any writing that was ever directed to AmerisourceBergen that said, "Your prior approval is no longer valid"?

A. I, I don't recall any type of correspondence specifically to AmerisourceBergen, no. But -- and I've got to go back and look, but I believe that was part of the 2005 distributor initiative. I don't have it handy, but --

Q. Well, right now I'm just asking you if anything -- you're aware of any writing that was issued under your -- while you were on your watch, for example, that was sent to AmerisourceBergen withdrawing approval of this, of this program?

A. I don't know of any, any type of correspondence that was sent specifically to AmerisourceBergen withdrawing that

program because I didn't know that program was approved, and I still don't. I'm not saying -- I just don't have any information because I was not back in headquarters in 1998. So I don't know if it was approved or not.

Q. So is it fair to say that as far as you personally know, this correspondence from you in December of 2007 would have been the first time that AmerisourceBergen was notified in writing that its prior approved program was no longer an approved program?

A. That letter --

MR. SINGER: Objection, Your Honor. This is contrary to the testimony here. Mr. Rannazzisi has testified that he didn't know that this was an approved program, and that it was policy not to approve programs. So I think the question mischaracterizes the testimony and it's misleading.

THE COURT: Well, the question was whether he knew of any prior notification that any program had not been approved. And that's a simple question. You can answer that.

THE WITNESS: And I don't know. I didn't know any program was approved. And, no, I don't know any program that -- you know, we didn't send any correspondence disapproving a program.

Q. Okay.

MR. NICHOLAS: I think we could probably -- I, I have more to do. It's a good time for a break if it's all right with the Court.

THE COURT: I assume you have more to go in the morning.

MR. NICHOLAS: I do.

THE COURT: And, Ms. Singer, you're going to have some redirect?

MS. SINGER: I expect it to be very brief, Your Honor.

THE COURT: Well --

MR. NICHOLAS: Do you want me to keep going?

THE COURT: How long do you think it will take?

MR. NICHOLAS: 20 minutes, you know. I feel bad, you know.

THE COURT: These things happen.

And you're going to have some redirect, Ms. Singer?

MR. SINGER: I expect to have some redirect. I will try to keep it brief, Your Honor, but probably about half an hour.

THE COURT: Okay.

Mr. Rannazzisi, it's probably cruel and unusual punishment, but I'm going to ask you to come back at 9:00 in the morning, sir, and we'll try to get you out of here sometime tomorrow morning.

THE WITNESS: I'm more than happy to, Judge. Thank you.

THE COURT: All right.

Ms. Singer, you're on your feet. Do you want to say something?

MR. SINGER: I just figured it would be more efficient. It seems we're moving towards a recess.

THE COURT: Well, I have no idea where this is going to go from here and I think, I think we'll recess until tomorrow morning at 9:00. I previously told you how unreliable I think lawyers can be and how much time they're going to take. I hesitate to go down this path. We'll see everybody in the morning.

(Trial recessed at 4:58 p.m.)

CERTIFICATION:

I, Ayme A. Cochran, Official Court Reporter, and I, Lisa A. Cook, Official Court Reporter, certify that the foregoing is a correct transcript from the record of proceedings in the matter of The City of Huntington, et al., Plaintiffs vs. AmerisourceBergen Drug Corporation, et al., Defendants, Civil Action No. 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as reported on June 9, 2021.

S\Ayme A. Cochran s\Lisa A. Cook

Reporter Reporter

June 9, 2021

Date

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